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

Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816.

Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association.

To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@aha.org.

The American Hospital Association (the “AHA”) has not reviewed, and is not responsible for, the completeness or accuracy of any information contained in this material, nor was the AHA or any of its affiliates, involved in the preparation of this material, or the analysis of information provided in the material. The views and/or positions presented in the material do not necessarily represent the views of the AHA. CMS and its products and services are not endorsed by the AHA or any of its affiliates.
Learn about these Clinical Laboratory Fee Schedule (CLFS) topics:

- Background
- Types of materials examined
- Clinical laboratory services coverage
- Summary of the private payor rate-based CLFS
- Advanced diagnostic laboratory tests (ADLTs)
- Resources

**BACKGROUND**

For services furnished through December 31, 2017:

- Prior to January 1, 2018, each Medicare Administrative Contractor (MAC) paid for clinical diagnostic laboratory tests (CDLTs) based on the local geographic area, and based fees on charges from laboratories in that geographic area.
- Payment was the lesser of: (1) the amount billed; (2) the local fee for a geographic area; or (3) a national limitation amount (NLA) for the HCPCS code.
- CLFS amounts could be updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers and a multi-factor productivity adjustment, but otherwise, they were not updated or changed.

Effective January 1, 2018:

- **Social Security Act (SSA) § 1834A**, as required by the Protecting Access to Medicare Act (PAMA) of 2014, made changes to how Medicare pays for CDLTs under the CLFS.
- The payment amount for most tests on the CLFS is equal to the weighted median of private payor rates. Payment rates under the private payor rate-based CLFS are generally updated every 3 years.
- The payment amounts established under the CLFS are not subject to any geographic adjustments.

**TYPES OF MATERIALS EXAMINED**

Clinical laboratories examine materials from the human body that give patient information for diagnosis, prevention, disease treatment, or to assess a medical condition, and include:

- 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 requires human laboratory specimen testing quality standards. The Secretary of the U.S. Department of Health and Human Services (HHS) must certify the laboratories that perform clinical tests. Medicare covers medically necessary and reasonable diagnostic clinical laboratory services to diagnose or treat an illness or injury.

Medicare covers diagnostic clinical laboratory services furnished in:
- Hospital laboratories (for outpatient or non-hospital 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), with certain exceptions.

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

For more information about covered screenings and preventive services, refer to the Preventive Services Provider Resources webpage.
SUMMARY OF THE PRIVATE PAYOR RATE-BASED CLFS

Under the private payor rate-based CLFS, reporting entities must report to the Centers for Medicare & Medicaid Services (CMS) certain private payor rate information (applicable information) for their component “applicable laboratories.” In general, the payment amount for a test on the CLFS, furnished on or after January 1, 2018, is equal to the weighted median of private payor rates determined for the test, based on the applicable information collected and reported to CMS during a data collection period. The data collection, reporting and payment updates generally occur every 3 years.

Additionally, SSA § 1834A and CMS regulations at 42 Code of Federal Regulations (CFR) § 414.507(d) limits the amounts the CLFS rates for most CDLTs can be reduced as compared to the payment rates for the preceding year. For the first 3 years after implementation (calendar year [CY] 2018 through CY 2020), the reduction cannot be more than 10 percent per year and for the next 3 years (CYs 2021 through 2023), the reduction cannot be more than 15 percent per year.

To be an “applicable laboratory,” a laboratory must meet the CLIA definition of a laboratory at 42 CFR § 493.2 and, by its own billing National Provider Identifier (NPI), must meet the “majority of Medicare revenues” threshold (that is, get more than 50 percent of its total Medicare revenues from the CLFS and/or PFS) and the low expenditure threshold (that is, get at least $12,500 in Medicare CLFS services revenues) during a data collection period.

The “applicable laboratory” is determined at the NPI level, but reporting the 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 an applicable laboratory:

1. Effective January 1, 2019, Medicare Advantage plan revenues are excluded from the majority of Medicare revenues threshold calculation.
2. Effective January 1, 2019, hospitals that bill non-patient laboratory services use Medicare revenues from Form CMS 1450 14X Type of Bill (TOB) to determine if its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

Additionally, for the January 1, 2021, through March 31, 2021, (previously January 1, 2020, through March 31, 2020) data reporting period, CMS will allow reporting entities to combine certain applicable information at the TIN level, instead of reporting for each “applicable laboratory” at the NPI level.

For new or substantially revised laboratory test codes and laboratory test codes for which CMS gets no applicable information during a data reporting period, the payment rate is based on “crosswalking” or “gapfilling” methodologies until private payor rate data is available for the next update. Under crosswalking, an existing test or combination of tests with similar methodology and resources is used as a basis for the payment amount. Gapfilling is used when there is no other test with similar methodology and resources. In this case, MACs develop a payment amount for the test.
ADVANCED DIAGNOSTIC LABORATORY TESTS

SSA § 1834A also created a new sub-category of CDLTs called advanced diagnostic laboratory tests (ADLTs). To qualify as an ADLT, the test must meet certain criteria. The test must:

- Be covered under Medicare Part B
- Be offered and furnished only by a single laboratory
- Not be sold for use by another laboratory except the single laboratory (or a successor owner)

ADLTs must also meet one of the following criteria:

- The test is cleared or approved by the U.S. Food and Drug Administration
- The test meets all the following criteria:
  - Is an analysis of multiple DNA, RNA, or protein biomarkers
  - 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
  - Gives new clinical diagnostic information unavailable from any other test or combination of tests
  - May include other assays

Generally, ADLTs are paid on the CLFS using the same methodology based on the weighted median of private payor rates as other CDLTs. However, new ADLTs are paid at a rate equal to their actual list charge during a new ADLT initial period of 3 calendar quarters. Once the new ADLT initial period is over, new ADLTs are paid based on the weighted median of private payor rates as other CDLTs. If no applicable information is available for an ADLT during a data reporting period, payment is determined based on either crosswalking or gapfilling methodologies.

While reporting is generally required every 3 years for CDLTs (that are not ADLTs), reporting entities must report applicable information annually for ADLTs, except for ADLTs in an initial data collection period (in which case a reporting entity will report by the end of the second quarter of the new ADLT initial period).

For a CDLT on the CLFS to be approved as an ADLT, an application to request ADLT status for the test must be submitted to CMS. 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, Medicare Part B Clinical Laboratory Fee Schedule: Revised Information for Laboratories on Collecting and Reporting Data for the Private Payor Rate-Based Payment System.
## Resources

### Table 1. CLFS Resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLFS</td>
<td>CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched</td>
</tr>
<tr>
<td></td>
<td>CMS.gov/Center/Provider-Type/Clinical-Labs-Center</td>
</tr>
<tr>
<td>CLFS Updates</td>
<td>CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files</td>
</tr>
<tr>
<td>Latest Updates on CLFS (annual laboratory public meetings)</td>
<td>CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings</td>
</tr>
<tr>
<td>Social Security Act (SSA) § 1833</td>
<td>SSA.gov/OP_Home/ssact/title18/1833.htm</td>
</tr>
<tr>
<td>Social Security Act (SSA) § 1861</td>
<td>SSA.gov/OP_Home/ssact/title18/1861.htm</td>
</tr>
</tbody>
</table>

### Table 2. Hyperlink Table

<table>
<thead>
<tr>
<th>Embedded Hyperlink</th>
<th>Complete URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 Code of Federal Regulations (CFR) § 414.507(d)</td>
<td><a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=e097ee2dd09dbdb77c03211bd7ff6bb&amp;mc=true&amp;node=pt42.3.414&amp;rgn=div5#se42.3.414_1507">https://www.ecfr.gov/cgi-bin/text-idx?SID=e097ee2dd09dbdb77c03211bd7ff6bb&amp;mc=true&amp;node=pt42.3.414&amp;rgn=div5#se42.3.414_1507</a></td>
</tr>
<tr>
<td>42 CFR § 493.2</td>
<td><a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=56bde913ecf3ba972ede535304137f6&amp;mc=true&amp;node=se42.5.493_12&amp;rgn=div8">https://www.ecfr.gov/cgi-bin/text-idx?SID=56bde913ecf3ba972ede535304137f6&amp;mc=true&amp;node=se42.5.493_12&amp;rgn=div8</a></td>
</tr>
<tr>
<td>Embedded Hyperlink</td>
<td>Complete URL</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>PAMA Regulations</td>
<td><a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations</a></td>
</tr>
<tr>
<td>Preventive Services Provider Resources</td>
<td><a href="https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/ProviderResources">https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/ProviderResources</a></td>
</tr>
<tr>
<td>Social Security Act (SSA) § 1834A</td>
<td><a href="https://www.ssa.gov/OP_Home/ssact/title18/1834A.htm">https://www.ssa.gov/OP_Home/ssact/title18/1834A.htm</a></td>
</tr>
</tbody>
</table>