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# Calendar Year (CY) 2022 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM12558 Revised Related Change Request (CR) Number: 12558

Related CR Release Date: January 12, 2022 Effective Date: January 1, 2022

Related CR Transmittal Number: R11186CP Implementation Date: January 3, 2022

Note: We revised this Article to reflect a revised CR 12558. The CR revision shows the delay in the CLFS data reporting period for clinical diagnostic laboratory tests and also the delay in the application of the 15% percent phase-in reduction. We revised the Article to show those delays. The changes are in dark red font on pages 1-2. We also revised the CR release date, transmittal number, and the web address of the CR. All other information is the same.

## **Provider Types Affected**

This MLN Matters Article is for laboratories submitting clinical laboratory claims to Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

#### **Provider Action Needed**

In this Article, you'll learn about:

- Instructions for the CY 2022 Clinical Laboratory Fee Schedule (CLFS)
- Mapping for new codes for clinical laboratory tests
- Updates for laboratory costs subject to the reasonable charge payment

Make sure your billing staff knows about these changes.

# **Background**

#### **Advanced Diagnostic Laboratory Tests (ADLTs)**

Refer to the CMS ADLT website for more information about these tests.

### **Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests**

Under the <u>CLFS final rule</u>, reporting entities must give CMS certain private payor rate





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information for their component applicable laboratories. On December 10, 2021, the <u>Protecting Medicare and American Farmers from Sequester Cuts Act</u> (S. 610) delayed the reporting requirement and also delayed the application of the 15% phase-in reduction.

- The next data reporting period of January 1, 2023–March 31, 2023. It will be based on the original data collection period of January 1, 2019–June 30, 2019. After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that aren't ADLTs (example: 2026, 2029)
- We're extending the statutory phase-in of payment reductions resulting from private payor rate implementation through CY 2024. There's a 0.0% reduction for CY 2021 and CY 2022. We won't reduce payment by more than 15% for CYs 2023–2025.

#### **CLFS Update to Fees**

For a Pap smear test, Section 1833(h)(7) of the Social Security Act (the Act) requires payment at the lesser of the local fee or the National Limitation Amount, but not less than a national minimum payment amount. However, for Pap smear tests, payment may also not exceed the actual charge. The CY 2022 national minimum payment amount is \$15.92 (This value reflects the CY 2021 national minimum payment with a 5.1% increase or \$15.15 times 1.051.) The affected codes for the national minimum payment amount are: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, Q0111, Q0115, and P3000.

The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2022 is 5.4% (See 42 CFR 405.509(b)(1)). Part B deductible and coinsurance don't apply for services paid under the CLFS.

#### **Access to Data File**

Other interested parties can get the <u>CY 2022 CLFS data file</u>. It will be available in multiple formats, including Excel®, text, and comma delimited.

#### **Public Comments and Final Payment Determinations**

On June 24, 2021, we hosted a public meeting to solicit comments on the CY 2021 reconsidered codes and new CY 2022 CPT codes. We got recommendations from many attendees, including individuals representing laboratories, manufacturers, and medical societies. A <u>summary of the meeting</u> is available. We accepted additional written comments from the public until October 22, 2021. A summary of the public comments and the rationale for the final payment determinations is available at this same site.

#### **Pricing Information**

The CY 2022 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615).

We update the fees for clinical laboratory travel codes P9603 and P9604 on an annual basis.





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The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. We'll issue a separate instruction on the clinical laboratory travel fees if there's a revision to the standard mileage rate for CY 2022.

The CY 2022 CLFS may also include codes that have a "QW" modifier to both identify codes and determine payment for tests you perform having only a CLIA certificate of waiver.

#### **Mapping Information**

Please see <u>Tab A (Mapping) of the table</u> that goes with CR 12558 for the mapping information for codes.

#### Laboratory Costs Subject to Reasonable Charge Payment in CY 2022

We pay hospital outpatient claims on a reasonable charge basis (See Section 1842(b)(3) of the Act.) The reasonable charge can't exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index (CPI) for the 12-month period ending June 30 of each year as set forth in 42 CFR 405.509(b)(1). The CPI update for CY 2022 is 5.40%.

Manual instructions for determining the reasonable charge payment are in the <u>Medicare Claims</u> <u>Processing Manual, Chapter 23</u>, Section 80 through 80.8. If there isn't enough charge data for a code, the instructions permit considering charges for other similar services and price lists.

Services described by HCPCS codes in the following list are performed for independent dialysis facility patients. Publication 100-04, <u>Medicare Claims Processing Manual, Chapter 8</u>, Section 60.3 instructs that the reasonable charge basis applies. However, when you perform these services for hospital-based renal dialysis facility patients, our payment is on a reasonable cost basis. Also, when you do these services for hospital outpatients, our payment is under the hospital Outpatient Prospective Payment System (OPPS).

#### **Blood Products, Transfusion Medicine, and Reproductive Medicine Procedures**

Please see Tab B (Reasonable Charge) of the table attached to the CR 12558.

#### New Code 0018M

The American Medical Association (AMA) CPT Editorial Panel established 1 new Multianalyte Assays with Algorithmic Analyses (MAAA) code, specifically, 0018M (Transplantation medicine [allograft rejection, renal], measurement of donor and third-party- induced CD154+Tcytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score), effective October 1, 2021. We added this code to the January 2022 CLFS.

#### **Proprietary Laboratory Analysis (PLAs)**

Please see Tab C (New Codes Eff. 1-1-2022) of the table attached to CR 12558. We added the





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listed new codes to the national HCPCS file with an effective date of January 1, 2022. These new codes are MAC-priced until we address them at the annual Clinical Laboratory Public Meeting in June or July 2022.

## **More Information**

We issued <u>CR 12558</u> to your MAC as the official instruction for this change.

For more information, find your MAC's website.

## **Document History**

Date of Change	Description
January 13, 2022	We revised this Article to reflect a revised CR 12558. The CR revision shows the delay in the CLFS data reporting period for clinical diagnostic laboratory tests and also the delay in the application of the 15% percent phase-in reduction. We revised the Article to show those delays. The changes are in dark red font on pages 1-2. We also revised the CR release date, transmittal number, and the web address of the CR. All other information is the same.
December 13, 2021	Initial article released.

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