| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 12426** | **Date: December 21, 2023** |
| | **Change Request 13467** |

**Transmittal 12389 issued November 30, 2023, is being rescinded and replaced by Transmittal 12426, dated December 21, 2023, to update the Calendar Year 2024 CLFS Annual Updates attachment. Thank you. All other information remains the same.**

**SUBJECT: Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment**

**I. SUMMARY OF CHANGES:** The purpose of this Recurring Update Notification (RUN) is to provide instructions for the CY 2023 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This RUN applies to chapter 16, section 20.

**EFFECTIVE DATE: January 1, 2024**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: January 2, 2024**

***Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.***

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| N/A | N/A |

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

| Pub. 100-04 | Transmittal: 12426 | Date: December 21, 2023 | Change Request: 13467 |
|---|---|---|---|

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**SUBJECT: Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment**

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**IMPLEMENTATION DATE: January 2, 2024**

## I. GENERAL INFORMATION

**A. Background:** This Recurring Update Notification (RUN) provides instructions for the CY 2024 clinical laboratory fee schedule (CLFS), mapping for new codes for clinical laboratory tests, updates for laboratory costs subject to the reasonable charge payment, and other CLFS related information. This RUN applies to chapter 16, section 20.

**B. Policy: <u>Clinical Laboratory Fee Schedule (CLFS)</u>**

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule "Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule" (CMS-1621-F) was published in the Federal Register on June 23, 2016. The CLFS final rule implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019 through June 30, 2019.

<u>Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests--DELAYED</u>

On November 16, 2023, Section 502 of the Further Continuing Appropriations and Other Extensions Act of 2024 was passed and delayed data reporting requirements for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests, and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation.

- The next data reporting period will be from January 1, 2025 – March 31, 2025 and based on the original data collection period of January 1, 2019 through June 30, 2019.
- A 0% payment reduction will be applied for CY 2024 so that a CDLT that is not an ADLT may not be reduced compared to the payment amount for that test in CY 2023, and for CYs 2025-2027 payment may not be reduced by more than 15 percent per year compared to the payment amount established for a test the preceding year.
- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2028, 2031, etc.).

Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following CMS website for additional information regarding these tests: https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs

Clinical Laboratory Fee Schedule Update to Fees

For a pap smear test, Section 1833(h)(7) of the Act requires payment to be 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 2024** national minimum payment amount is **$17.76** (This value reflects the **CY 2023** national minimum payment with a **2.6 percent**increase or **$17.31 times 1.026**). 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 is the CPI-U, which for **CY 2024 is 3.0 percent**(See 42 CFR 405.509(b)(1)).

The Part B deductible and coinsurance do not apply for services paid under the CLFS.

Access to Data File

The CY 2024 CLFS data file shall be retrieved electronically through CMS' mainframe telecommunications system. A/B MAC contractors shall retrieve the data file on or after December 1, 2023.

The January 1, 2024 CY 2024 CLFS Public Use File (PUF) will be available on the CMS website in the last week of December, at https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files. The CLFS PUF is available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 22, 2023, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2023 and new CY 2024 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the **Federal Register**on April 14, 2023 (CMS-1796-N). Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted proposed payment determinations on the web site at https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings. Additional written comments from the public were accepted until October 27, 2023. CMS also posted a summary of the public comments and the rationale for the final payment determinations at the same CMS web site identified in the previous sentence.

Pricing Information

The CY 2024 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, P9615, and G0471). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.

The fees for clinical laboratory travel codes P9603 and P9604 are updated on an annual basis. The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2024, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2024 clinical laboratory fee schedule may also include codes that have a “QW” modifier to both identify codes and determine payment for tests performed by a laboratory having only a CLIA certificate of waiver. Code will be listed if applicable.

Mapping Information

Please see table attached to the Transmittal entitled "CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment", Tab "**A. Mapping Information,**" which lists the mapping information for codes.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2024

Hospital outpatient claims are paid under a reasonable charge basis (See Section 1842(b)(3) of the Act). In accordance with 42 CFR 405.502 through 42 CFR 405.508, the reasonable charge may not 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 2024 is **3.0 percent.**

Manual instructions for determining the reasonable charge payment can be found in publication 100-04, Medicare Claims Processing Manual, chapter 23, section 80 through 80.8. If there is not sufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

Services described by Healthcare Common Procedural Coding System (HCPCS) codes in the following list are performed for independent dialysis facility patients. Publication 100-04, Medicare Claims Processing Manual, chapter 8, section 60.3 instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the hospital Outpatient Prospective Payment System (OPPS).

*Blood Products*

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**B. Reasonable Charge.**"

*Transfusion Medicine*

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**B. Reasonable Charge.**"

*Reproductive Medicine Procedures*

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**B. Reasonable Charge.**"

*New Codes*

*Proprietary Laboratory Analysis (PLAs)*

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**C. New Codes Eff. 1-1-2024.**"

The listed new codes have been added to the national HCPCS file with an effective date of January 1, 2024 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment

determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

MACs shall only price PLA codes for laboratories within their jurisdiction.

**Deleted Codes Effective January 1, 2024**

Please see table attached to the Transmittal entitled "**CY2024 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment,**" Tab "**D. Deleted Codes Eff. 1-1-2024.**"

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 13467.1 | A/B MAC Parts A and B contractors shall retrieve and implement the CY 2024 Clinical Laboratory Fee Schedule data files<br><br>(filenames:<br><br>MU00.@BF12394.CLAB.V2024Q1.FULLREPL<br><br>MU00.@BF12394.CLAB.V2024Q1.UPDTONLY) from the CMS mainframe on or after December 1, 2023. Please note that the two data files will have the same contents since all records will have an update. | X | X | | | | | | | |
| 13467.1.1 | A/B MAC Part B contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., A/B MAC Part B name and number). | | X | | | | | | | VDCs |
| 13467.1.2 | A/B MAC Part A contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., A/B MAC Part A name and number). | X | | | | | | | | VDCs |
| 13467.2 | Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should | X | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | adjust claims if they are brought to their attention. | | | | | | | | | |
| 13467.3 | A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis. | | X | | | | | | | |
| 13467.4 | A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2022 through June 30, 2023, updated by the inflation-index update for year CY 2024 of 3.0 percent. | | X | | | | | | | |
| 13467.5 | A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients. | X | | | | | | | | |
| 13467.6 | CMS shall issue a separate instruction on the clinical laboratory travel fees, if there is a revision to the standard mileage rate for CY 2024. | | | | | | | | | CMS |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| 13467.7 | Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track | X | X | | | |

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| | and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above. | | | | | |

## IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements:** N/A

*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|

**Section B: All other recommendations and supporting information:** N/A

## V. CONTACTS

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**
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**ATTACHMENTS: 1**