

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11186	Date: January 12, 2022
	Change Request 12558

Transmittal 11151, dated December 10, 2021, is being rescinded and replaced by Transmittal 11186, dated, January 12, 2022 to revise the policy section to reflect the delay in the CLFS data reporting period for clinical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. All other information remains the same.

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

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the CY 2022 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, 2022

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 3, 2022

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

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I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides 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, and other CLFS related information. This RUN applies to chapter 16, section 20.

B. Policy: Clinical Laboratory Fee Schedule

Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following CMS website for additional information regarding these tests:
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations>

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests--DELAYED

On December 10, 2021, the “Protecting Medicare and American Farmers from Sequester Cuts Act” (S. 610) delayed the reporting requirement under Section 1834A of the Act and also delayed the application of the 15% phase-in reduction.

- 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.
- The next data reporting period of January 1, 2023 through March 31, 2023, will be based on the original data collection period of January 1, 2019 through June 30, 2019.
- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2026, 2029, etc.).

- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2025. There is a 0.0 percent reduction for CY 2021 and CY 2022, and payment may not be reduced by more than 15 percent for CYs 2023 through 2025.

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 2022** national minimum payment amount is **\$15.92** (This value reflects the **CY 2021** national minimum payment with a **5.1 percent** 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 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 2022 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, 2021. Internet access to the CY 2022 CLFS data file shall be available after December 1, 2021, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. Other interested parties shall use the Internet to retrieve the CY 2022 CLFS. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 24, 2021, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2021 codes and new CY 2022 Current Procedural Terminology (CPT) codes. Notice of the meeting was published in the **Federal Register** on May 3, 2021. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations on the web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. Additional written comments from the public were accepted until October 22, 2021. 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 2022 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). 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 2022, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2022 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 "CY2022 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 2022

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 2022 is **5.40 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 "CY2022 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 "CY2022 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 "CY2022 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment", Tab "**B. Reasonable Charge**".

New Code 0018M

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

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "CY2022 CLFS Annual Updates and Laboratory Services Subject to Reasonable Charge Payment", Tab "**C. New Codes Eff. 1-1-2022**". The listed new codes have been added to the national HCPCS file with an effective date of January 1, 2022 and do not need

to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2022 as they were received after the 2021 public meeting.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
12558.1	A/B MAC Parts A and B contractors shall retrieve and implement the CY 2022 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.V2022 Q1) from the CMS mainframe on or after December 1, 2021.	X	X							
12558.1.1	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							VDC s
12558.1.2	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								VDC s
12558.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X							
12558.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge		X							

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	basis.									
12558.4	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2020 through June 30, 2021, updated by the inflation-index update for year CY 2022 of 5.4 percent.		X							
12558.5	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								
12558.6	If there is a revision to the standard mileage rate for CY 2022, CMS shall issue a separate instruction on the clinical laboratory travel fees.									CMS

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12558.7	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 and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X			

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

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@cms.hhs.gov , Laura Ashbaugh, 410-786-1113 or laura.ashbaugh2@cms.hhs.gov

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

VI. FUNDING

Section A: 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.

ATTACHMENTS: 1