

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10853	Date: June 15, 2021
	Change Request 12285

Transmittal 10810, dated May 20, 2021, is being rescinded and replaced by Transmittal 10853, dated, June 15, 2021 to revise the policy section and to add an updated July PLA Codes attachment. All other information remains the same.

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: July 1, 2021

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

IMPLEMENTATION DATE: July 6, 2021

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: 10853	Date: June 15, 2021	Change Request: 12285
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SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: July 1, 2021

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

IMPLEMENTATION DATE: July 6, 2021

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. 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.html#ADLT_tests.

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

- 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.
- Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. In summary, revisions are as follows:
 - The next data reporting period of January 1, 2022 through March 31, 2022, 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 2025, 2028, etc.).
 - The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2024. There is a 0.0 percent reduction for

CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024.

Clinical Laboratory Fee Schedule Beginning January 1, 2018

- Effective January 1, 2018, CLFS rates are based on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014.
- The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.
- For more details, visit PAMA Regulations, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>.
- **Access to Data File:** The quarterly clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. Under normal circumstances, CMS will make the updated CLFS data file available to A/B MAC contractors approximately 6 weeks prior to the beginning of each quarter. For example, the updated file will typically be made available for download and testing on or before approximately February 15th for the April 1st release. Internet access to the quarterly clinical laboratory fee schedule data file shall be available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, shall use the Internet to retrieve the quarterly clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.
- **Pricing Information:** The clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees are established in accordance with section 1833(h)(4)(B) of the Act. Also note additional specimen collection codes may be listed below during the PHE.

New Codes Effective July 1, 2021

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**New Codes Effective July 1, 2021***", Tab "**New Codes**". The listed new codes were added to the national HCPCS file with an effective date of July 1, 2021 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.

The table includes the laboratory, long descriptor, short descriptor, and TOS of each new code.

Additional Codes

Please see table attached to the Transmittal entitled "**New Codes Effective July 1, 2021***", Tab "**New Codes**". The additional listed new codes were added to the national HCPCS file with an effective date of July 1, 2021 (code G0327), and April 1, 2021 (code 0017M), in addition to the PLA codes, 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

Number	Requirement	Responsibility									
		A/B MAC		D M E	Shared-System Maintainers				Other		
		A	B		H H H	F M V C	I C M W	S S S F			
	their attention.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC			D M E	C E D I		
		A	B	H H H			M A C	
12285.7	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	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:

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

V. CONTACTS

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

New Codes Effective July 1, 2021*

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of July 1, 2021 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.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
3D Predict Glioma, KIYATEC®, Inc	0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	ONC BRN SPHRD CLL 12 RX PNL	5	07/01/21
Theralink® Reverse Phase Protein Array (RPPA), Theralink® Technologies, Inc, Theralink® Technologies, Inc	0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	ONC BRST ALYS 32 PHSPRTN ALG	5	07/01/21
PGDx elioTM tissue complete, Personal Genome Diagnostics, Inc, Personal Genome Diagnostics, Inc	0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	ONC SLD ORG NEO DNA 505 GENE	5	07/01/21
Intrinsic Hepcidin IDxTM Test, IntrinsicDx, Intrinsic LifeSciencesTM LLC	0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	HEPCIDIN-25 ELISA SERUM/PLSM	5	07/01/21
POC (Products of Conception), Igenomix®, Igenomix® USA	0252U	Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	FTL ANEUPLOIDY STR ALYS DNA	5	07/01/21
ERA® (Endometrial Receptivity Analysis), Igenomix®, Igenomix® USA	0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)	RPRDIVE MED RNA GEN PRFL 238	5	07/01/21
SMART PGT-A (Preimplantation Genetic Testing - Aneuploidy), Igenomix®, Igenomix® USA	0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested	REPRDIVE MED ALYS 24 CHRMSM	5	07/01/21

Additional Codes

The following new codes have been added to the national HCPCS file 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).

* In addition, we are adding code 0017M, effective April 1, 2021. This code was erroneously omitted from previous submissions and is therefore added here.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
	G0327	Colorectal cancer screening; blood-based biomarker	Colon ca scrn;bid-bsd biomrk	5	07/01/21
Lymph2Cx, Mayo Clinic Arizona Molecular Diagnostics Laboratory	0017M	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffinembedded tissue, algorithm reported as cell of origin	Onc dlbcl mrna 20 genes alg	5	04/01/21