

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 4090</b>	<b>Date: July 20, 2018</b>
	<b>Change Request 10875</b>

**SUBJECT: Quarterly 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 quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

**EFFECTIVE DATE: October 1, 2018**

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

**IMPLEMENTATION DATE: October 1, 2018**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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: 4090	Date: July 20, 2018	Change Request: 10875
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**SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment**

**EFFECTIVE DATE: October 1, 2018**

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**IMPLEMENTATION DATE: October 1, 2018**

## 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:** Effective January 1, 2018, Clinical Laboratory Fee Schedule (CLFS) rates will be based on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. For more details, visit PAMA Regulations, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>.

The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

### Access to Data File

The quarterly clinical laboratory fee schedule data file shall be retrieved electronically through Centers for Medicare & Medicaid Services' (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 May 15th for the July 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.

### New Codes

The following new codes will be contractor priced, until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in July, 2018. The following "U" codes shall have Healthcare Common Procedure Coding System (HCPCS) Pricing Indicator Code - 22 = Price established by A/B MACs Part B (e.g., gap-fills, A/B MACs Part B established panels) instead of Pricing Indicator - 21 = Price Subject to National Limitation Amount. (Code, Long Descriptor, Short Descriptor, Effective Date, Type of Service (TOS)).

The following new codes are effective July 1, 2018:

0045U TOS 5; Short Descriptor—ONC BRST DUX CARC IS 12 GENE; Long Descriptor—Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score

0046U TOS 5; Short Descriptor—FLT3 GENE ITD VARIANTS QUAN; Long Descriptor—FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative

0047U TOS 5; Short Descriptor—ONC PRST8 MRNA 17 GENE ALG; Long Descriptor—Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score

0048U TOS 5; Short Descriptor—ONC SLD ORG NEO DNA 468 GENE; Long Descriptor—Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)

0049U TOS 5; Short Descriptor—NPM1 GENE ANALYSIS QUAN; Long Descriptor—NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, quantitative

0050U TOS 5; Short Descriptor—TRGT GEN SEQ DNA 194 GENES; Long Descriptor—Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements

0051U TOS 5; Short Descriptor—RX MNTR LC-MS/MS UR 31 PNL; Long Descriptor—Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service

0052U TOS 5; Short Descriptor—LPOPRTN BLD W/5 MAJ CLASSES; Long Descriptor—Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation

0053U TOS 5; Short Descriptor—ONC PRST8 CA FISH ALYS 4 GEN; Long Descriptor—Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade

0054U TOS 5; Short Descriptor—RX MNTR 14+ DRUGS & SBSTS; Long Descriptor—Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service

0055U TOS 5; Short Descriptor—CARD HRT TRNSPL 96 DNA SEQ; Long Descriptor—Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma

0056U TOS 5; Short Descriptor—HEM AML DNA GENE REARGMT; Long Descriptor—Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)

0057U TOS 5; Short Descriptor—ONC SLD ORG NEO MRNA 51 GENE; Long Descriptor—Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank



Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
10875.2	Contractors shall retrieve and load for testing and claims processing purposes the October 2018 quarterly CLFS data file from the CMS mainframe on or after August 15, 2018.	X	X								VDCs
10875.2.1	Contractors shall note that the CLFS data file name will be in the following format:  MU00.@BF12394.CLAB.V2018Q4	X	X								VDCs
10875.2.2	Contractors shall notify CMS of successful receipt via email to price_file_receipt@cms.hhs.gov stating the name of the file received, (e.g., CLAB, ASP, etc.) and the entity for which it was received (i.e., include states, carrier numbers, quarter, and if Part A, Part B, or both).	X	X								VDCs
10875.2.3	Contractors shall address any questions/concerns regarding the content of the files and/or specific HCPCS codes contained within by emailing CLFS_Inquiries@cms.hhs.gov.	X	X								VDCs
10875.3	Contractors shall be aware of any new Advanced Diagnostic Laboratory Test (ADLT) codes, and/or Current Procedural Terminology (CPT)/HCPCS codes (including their Type of Service (TOS) designation(s) and Effective date), and/or any deleted/terminated codes as applicable listed in this Change Request and shall update their systems as necessary to accept/delete/terminate them.	X	X							X	
10875.3.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (IOCE) update, contractors shall locally price the codes until they appear on the CLFS file and/or, for Part A claims, the IOCE.	X	X								
10875.4	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								

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C E D I
		A	B	H H H		
10875.5	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):** 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):**

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**ATTACHMENTS: 0**