

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4045	Date: May 11, 2018
	Change Request 10642

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: July 1, 2018

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

IMPLEMENTATION DATE: July 2, 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.

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

EFFECTIVE DATE: July 1, 2018

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IMPLEMENTATION DATE: July 2, 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 April 1, 2018:

0035U TOS 5; Short Descriptor—Neuro csf prion prtn qual; Long Descriptor—Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative

0036U TOS 5; Short Descriptor—Xome tum & nml spec seq alys; Long Descriptor—Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses

0037U TOS 5; Short Descriptor—Trgt gen seq dna 324 genes; Long Descriptor—Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden

0038U TOS 5; Short Descriptor—Vitamin d srm microsamp quan; Long Descriptor—Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative

0039U TOS 5; Short Descriptor—Dna antb 2strand hi avidity; Long Descriptor—Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity

0040U TOS 5; Short Descriptor—Bcr/abl1 gene major bp quan; Long Descriptor—BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative

0041U TOS 5; Short Descriptor—B brgdrferi antb 5 prtn igm; Long Descriptor—Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM

0042U TOS 5; Short Descriptor—B brgdrferi antb 12 prtn igg; Long Descriptor—Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG

0043U TOS 5; Short Descriptor—Tbrf b grp antb 4 prtn igm; Long Descriptor—Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM

0044U TOS 5; Short Descriptor—Tbrf b grp antb 4 prtn igg; Long Descriptor—Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG

0012M TOS 5; Short Descriptor—Onc mrna 5 gen risk urthl ca; Long Descriptor—Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma

0013M TOS 5; Short Descriptor—Onc mrna 5 gen recr urthl ca; Long Descriptor—Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma

The following new code is effective January 1, 2018:

0011M TOS 5; Short Descriptor—Onc prst8 ca mrna 12 gen alg; Long Descriptor—Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk

II. BUSINESS REQUIREMENTS TABLE

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

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		
	Part A claims, the IOCE.										
10642.4	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		H H H	D M E M A C	C E D I					
		A	B								
10642.5	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	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

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