

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3999	Date: March 14, 2018
	Change Request 10445

Transmittal 3973, dated February 8, 2018, is being rescinded and replaced by Transmittal 3999, dated, March 14, 2018 to remove the list of new codes with a QW modifier that were effective as of April 1, 2018 from the policy section. All other information remains the same.

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: January 1, 2018 - For new HCPCS codes listed in the Background section; April 1, 2018

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

IMPLEMENTATION DATE: April 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/revise 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: 3999	Date: March 14, 2018	Change Request: 10445
-------------	-------------------	----------------------	-----------------------

Transmittal 3973, dated February 8, 2018, is being rescinded and replaced by Transmittal 3999, dated, March 14, 2018 to remove the list of new codes with a QW modifier that were effective as of April 1, 2018 from the policy section. All other information remains the same.

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

EFFECTIVE DATE: January 1, 2018 - For new HCPCS codes listed in the Background section; April 1, 2018

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

IMPLEMENTATION DATE: April 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: Fee Schedule Beginning January 1, 2018

Effective January 1, 2018, 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 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.

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 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))

0024U Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative
GLYCA NUC MR SPECTRSC QUAN 1/1/2018 5

0025U Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine,
quantitative TENOFOVIR LIQ CHROM UR QUAN 1/1/2018 5

0026U Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate
of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of
malignancy" or "Negative, low probability of malignancy") ONC THYR DNA&MRNA 112 GENES 1/1/18
5

0027U JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis
exons 12-15 JAK2 GENE TRGT SEQ ALYS 1/1/18 5

0028U CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene
analysis, copy number variants, common variants with reflex to targeted sequence analysis CYP2D6 GENE
CPY NMR CMN VRNT 1/1/18 5

0029U Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie,
CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and
rs12777823) RX METAB ADVRS TRGT SEQ ALYS 1/1/18 5

0030U Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2,
VKORC1, rs12777823) RX METAB WARF TRGT SEQ ALYS 1/1/18 5

0031U CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis,
common variants (ie, *1F, *1K, *6, *7) CYP1A2 GENE 1/1/18 5

0032U COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant
COMT GENE 1/1/18 5

0033U HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg,
citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C
rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G]) HTR2A HTR2C GENES 1/1/18 5

0034U TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine
metabolism), gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15
*3, *4, *5) TPMT NUDT15 GENES 1/1/18 5

The following new codes are effective January 1, 2018:

New code 87634QW is priced at the same rate as code 87634.

Deleted Codes

The following codes are deleted effective January 1, 2018:

Existing code 0004U is to be deleted.

Existing code 0015U is to be deleted.

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			
10445.2.3	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								VDC	
10445.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis (**NOTE** - This requirement is applicable to the January quarterly release CR only).		X									
10445.4	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 (**NOTE** - This requirement is applicable to the January quarterly release CR only).	X										
10445.5	Contractors shall be aware of any new Advanced Diagnostic Laboratory Test (ADLT) codes, and/or CPT/HCPCS codes (including their 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		
10445.5.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly 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									
10445.6	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 M A C	C E D I
		A	B	H H H		
10445.7	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:

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

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, 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: 0