CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12534	**Date: March 7, 2024**
	Change Request 13546

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, the CMS must notify its contractors of the new tests so that the contractors can accurately process claims. There are 25 newly added waived complexity tests. This recurring update notification applies to chapter 16, section 70.8 of the Internet Only Manual (IOM).

EFFECTIVE DATE: April 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 1, 2024

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: 12534	Date: March 7, 2024	Change Request: 13546

SUBJECT: New Waived Tests

EFFECTIVE DATE: April 1, 2024
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IMPLEMENTATION DATE: April 1, 2024

I. GENERAL INFORMATION

A. Background: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Listed below is the latest test(s) approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The Healthcare Common Procedure Coding System (HCPCS) codes for the following new test(s) must have the modifier QW to be recognized as a waived test(s).

The HCPCS code, effective date, and description for the latest test(s) approved by the FDA as waived test(s) under CLIA is the following:

CODE EFFECTIVE DATE TEST/MANUFACTURER

- 0352UQW October 19, 2023, Cepheid GeneXpert Xpress System {Xpert Xpress MVP} Under Proprietary Laboratory Analyses
- 82274QW, G0328QW November 13, 2023, Rodimedi & Associates Inc. RedTunica iFOB One Step Rapid Test
- 80305QW November 16, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methamphetamine (MET/mAMP) Urine Test Panel
- 80305QW November 17, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methadone (MTD) Urine Test Panel
- 80305QW November 30, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methylenedioxymethamphetamine (MDMA) Urine Test Panel
- 82274QW, G0328QW November 30, 2023, Diacarta INC. iCOLON iFOB TEST immunochemical Fecal Occult Blood Test (See analysis tab)
- 82274QW, G0328QW November 30, 2023, DiaCarta Inc. iCOLON iFOB TEST immunochemical Fecal Occult Blood Test
- 82274QW, G0328QW December 01, 2023, DiaCarta Inc iCOLON iFOB TEST immunochemical Fecal Occult Blood Test
- 80305QW December 22, 2023, McKesson Medical-Surgical Inc. McKesson Consult Fentanyl Urine Test Cassette
- 80305QW December 05, 2023, American Screening Corp Discover Fentanyl Rapid Test Cassette
- 80305QW December 05, 2023, Verify Diagnostics Inc. VeriCheck Drug Test Cup (Urine)
- 80305QW December 06 ,2023, CLIAWaived Inc. Test Yourself At Home Home Rapid Test Cup (Urine)
- 80305QW December 06, 2023, CLIAwaived Inc. Rapid Drug Test Device "RDTD" for Fentanyl in Urine
- 80305QW December 06, 2023, Instant Technologies Inc. iCassette Fentanyl Urine Test Cassette
- 80305QW December 06, 2023, Healgen Scientific LLC Healgen Drug of Abuse Urine Quick Split Cup

- 80305QW December 07, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methamphetamine (MET500/mAMP500) Urine Test Panel
- 80305QW December 14, 2023, Wondfo USA Co. Ltd SAFElife Cannabinoids (THC) Urine Test
- 87400QW December 14,2023, Becton Dickinson and Company BD Veritor Plus Analyzer {BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit} (For use with nasal swabs only)
- 80305QW December 15, 2023, Hangzhou AllTest Biotech Co. Ltd. AllTest Multi-Drug Rapid Test Panel
- 80305QW December 15, 2023, Hangzhou AllTest Biotech Co. Ltd. AllTest Multi-Drug Rapid Test Cup
- 80305QW December 18, 2023, Wondfo USA Co Ltd. SAFElife T-Dip Propoxyphene (PPX) Urine Test Panel
- 80305QW December 18, 2023, Preferred Med Supply #1 Best Multi-Panel Drug Test Cup
- 80305QW December 22, 2023, McKesson Medical-Surgical Inc. McKesson Consult Fentanyl Urine Test Cassette
- 80305QW December 22, 2023, Guangzhou Decheng Biotechnology Co. Ltd. Dochek Multi-Drug Urine Test Cup
- 80305QW December 27, 2023, Medical Distribution Group Inc. Identify Diagnostics Fentanyl Urine Cassette

This recurring update notification applies to chapter 16, section 70.8 of the IOM.

Note: FDA approval information about the test(s), and their use, can be found by using the search feature at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm and referring to the FDA Review Decision Summary documentation about the test(s).

B. Policy: The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13546.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X							
13546.2	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							
13546.3	Contractors shall not use, as a reason for rejecting a claim, the explanatory information found		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	in the FDA Review Decision Summary documentation for the lab test(s) above when using the FDA website above to determine a test's use.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13546.4	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

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

V. CONTACTS

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