CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13218	**Date: May 9, 2025**
	Change Request 14025

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 six (6) newly added waived complexity tests. This recurring update notification applies to chapter 16, section 70.8 of the Internet Only Manual (IOM).

EFFECTIVE DATE: July 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 7, 2025

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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II. 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:

HCPCS Code	Effective Date	Description
G0567QW	June 27, 2024	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, screening, amplified probe technique
87563QW	January 16, 2025	Mycoplasma genitalium, amplified probe technique infectious agent detection by nucleic acid (DNA or RNA)
87491QW	January 16, 2025	Chlamydia trachomatis, amplified probe technique infectious agent detection by nucleic acid (DNA or RNA)
87591QW	January 16, 2025	Neisseria gonorrhoeae, amplified probe technique infectious agent detection by nucleic acid (DNA or RNA)
0563UQW	July 1, 2025	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
0564UQW	July 1, 2025	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative

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.

III. 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	
14025.1	Contractors shall include the new test(s) listed above in CLIA-covered code files with the QW modifier.		X							
14025.2	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							
14025.3	Contractors shall not use, as a reason for rejecting a claim, the explanatory information found 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.		X							
14025.4	Contractors shall permit the use of code G0567QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after June 27, 2024, the use of codes 87563QW, 87491QW, and 87591QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 16, 2025, and the use of codes		X						X	CVM

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	0563UQW and 0564UQW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after July 1, 2025.									

IV. PROVIDER EDUCATION

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.

Impacted Contractors: A/B MAC Part B

V. 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

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0