

New Waived Tests

Related CR Release Date: May 9, 2025	MLN Matters Number: MM14025
Effective Date: July 1, 2025	Related Change Request (CR) Number: <u>CR 14025</u>
Implementation Date: July 7, 2025	Related CR Transmittal Number: R13218CP

Affected Providers

- Hospitals
- Physicians
- Suppliers

Action Needed

Make sure your billing staff knows about these updates:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- New FDA-approved waived tests
- The code, effective date, and description for the latest waived tests

Background

Facilities must have appropriate certification to perform tests per CLIA regulations. We edit laboratory claims at the CLIA certificate level to ensure Medicare only pays for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver.

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Key Updates

FDA has approved 6 new waived tests under CLIA. Include the QW modifier to make sure we recognize these CPT and HCPCS codes as waived tests.

See the table below for the codes, effective dates, and descriptions.

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	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma genitalium, amplified probe technique
87491QW	January 16, 2025	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87591QW	January 16, 2025	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique
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

To learn more about these tests and their use:

- Use the FDA search feature
- Refer to the FDA Review Decision Summary documentation about these tests

Note: Medicare Administrative Contractors (MACs) won't search their files to either retract payment or retroactively pay claims. However, MACs will adjust claims if you bring them to their attention.

More Information

We issued CR 14025 to your MAC as the official instruction for this change. For more information, find your MAC's website.

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Document History

Date of Change	Description
May 9, 2025	Initial article released.

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