



New Waived Tests

Related CR Release Date: August 22, 2024

MLN Matters Number: MM13757

Effective Date: October 1, 2024

Related Change Request (CR) Number: [CR 13757](#)

Implementation Date: October 7, 2024

Related CR Transmittal Number: R12808CP

Affected Providers

- Hospitals
- Physicians
- Suppliers

Action Needed

Make sure your billing staff knows about:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- New CLIA-waived test approved by the FDA
- Use of modifier QW for CLIA-waived tests

Background

CLIA regulations require a facility to be appropriately certified for each test they do. CMS edits laboratory claims at the CLIA certificate level to make sure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate.

Listed below is the latest test the FDA approved as a waived test under CLIA. The HCPCS code for the following new test must have the modifier QW to be recognized as a waived test.

The HCPCS code, effective date, and description for this waived test under CLIA is:

Code	Effective Date	Test/Manufacturer
87521QW System {Xpert HCV}	June 27, 2024	Cepheid GeneXpert Xpress

Find FDA approval information about these tests and their use by:

- Using the [FDA search feature](#)

- Referring to the FDA Review Decision Summary documentation about the tests

Medicare Administrative Contractors (MACs) won't search their files to either take back payment or retroactively pay claims affected by CR 13757. They'll adjust claims you bring to their attention.

More Information

We issued CR 13757 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
August 26, 2024	Initial article released.

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