



New Waived Tests

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Related Change Request (CR) Number: 12504

Related CR Release Date: October 28, 2021

Effective Date: January 1, 2022

Related CR Transmittal Number: R11082CP

Implementation Date: January 3, 2022

Provider Types Affected

This MLN Matters Article is for providers billing Medicare Administrative Contractors (MACs) for Clinical Laboratory Improvement Amendments (CLIA) waived laboratory tests they provide to Medicare patients.

Provider Action Needed

In this Article, you will learn about:

- CLIA requirements
- New CLIA waived tests approved by the FDA
- Use of modifier QW for CLIA-waived tests

Make sure your billing staff knows about these changes.

Background

The CLIA regulations require a facility to be appropriately certified for each test performed. Laboratory claims are currently edited at the CLIA certificate level to make sure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver.

Since these tests are marketed immediately after approval, CMS must notify its MACs of the new tests so they process claims accurately. There are 3 newly added waived complexity tests.

Listed below are the latest tests the FDA approved as waived tests under CLIA. These new tests must have the modifier QW to be recognized as a waived test.

The HCPCS code, effective date and description for these latest tests are:

- 87801QW, March 30, 2021, binx health io Instrument {For use with female vaginal swabs and male urine}
- 86308QW, August 9, 2021, Cardinal Health Mono Rapid Test (Whole blood)

- 87801QW, August 26, 2021, Visby Medical Sexual Health Click Test (For use with self-collected vaginal swabs)

The new HCPCS code 87801QW (Detection test by nucleic acid for multiple organisms, amplified probe(s) technique) was assigned for the waived complexity testing performed by the binx health io Instrument (For use with female vaginal swabs and male urine) and the Visby Medical Sexual Health Click Test (For use with self-collected vaginal swabs). This code is effective March 30, 2021.

The tests on the first page of the [list attached to CR 12504](#) (that's, HCPCS codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) don't require a QW modifier to be recognized as a waived test.

MACs won't search their files to either take back payment or retroactively pay claims affected by CR 12504. They should adjust such claims that you bring to their attention.

More Information

We issued [CR 12504](#) to your MAC as the official instruction for this change.

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

Document History

| Date of Change | Description |
|------------------|---------------------------|
| November 1, 2021 | Initial article released. |

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