



New Waived Tests

Related CR Release Date: June 15, 2023

MLN Matters Number: MM13253

Effective Date: October 1, 2023

Related Change Request (CR) Number: [CR 13253](#)

Implementation Date: October 2, 2023

Related CR Transmittal Number: R12089CP

Related CR Title: New Waived Tests

Affected Providers

- Physicians
- Providers
- Suppliers

Action Needed

Make sure your billing staff knows about:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- New CLIA-waived tests 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.

Since these tests are marketed immediately after approval, we tell the Medicare Administrative Contractors (MACs) of the new tests so they process claims accurately. There are 6 newly added waived complexity tests. 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:

- 87633QW, February 3, 2023, BIOFIRE Diagnostics, BIOFIRE SPOTFIRE System
- 87801QW, March 7, 2023 Visby Medical Inc., Visby Medical Sexual Health Test (For use with self-collected vaginal swabs)
- 80305QW, March 21, 2023, Healgen Scientific LLC, Healgen Accurate Oral Fluid Drug Test COT
- 80305QW, April 14, 2023 Shenzhen Bioeasy Biotechnology Co., Ltd., U-Catch MAX Multi-Drug Test Cup

- 80305QW, April 28, 2023, Medical Disposables Corp., ON-Site One Step Drug Test Cup
- 80305QW, April 28, 2023, Medical Disposables Corp., ON-Site One Step Drug Test Dip Card

The tests on the first page of the list attached to CR 13253, which are 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 13253. They'll adjust claims you bring to their attention.

More Information

We issued CR 13253 to your MAC as the official instruction for this change.

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

Document History

Date of Change	Description
June 15, 2023	Initial article released.

View the [Medicare Learning Network® Content & Product Disclaimer, and Department of Health & Human Services Disclosure](#).

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health & Human Services (HHS).