



New Waived Tests

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Related Change Request (CR) Number: 12841

Related CR Release Date: August 4, 2022

Effective Date: October 1, 2022

Related CR Transmittal Number: R11547CP

Implementation Date: October 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

Make sure your billing staff knows about these changes:

- 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 MACs of the new tests, so they process claims accurately. There are 8 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:

- 87651QW, November 09, 2020, Mesa Biotech Accula {Accula Strep A Test}
- G0475QW, February 07, 2022, Abbott Diagnostics Determine HIV-1/2 Ag/Ab Combo {Fingerstick whole blood}
- 80305QW, March 01, 2022, Noble Medical Inc. Noble Dip Card/Drug Test Cup
- 82465QW, March 25, 2022, PTS Panels Cholesterol Test Strips, Polymer Technology Systems Inc. CardioChek Plus Test System {PTS Panels Cholesterol Test Strips}
- 82010QW, 82962, April 07, 2022, Apex Biotechnology Corp. MTM301 Blood Glucose and Ketone Monitoring System

- 80305QW, May 09, 2022, T&D Diagnostics Canada Pvt. Ltd. Sienna Multi-Drug Test (Cup and Dip Card)
- 80305QW, June 01, 2022, NexScreen Gen2 Multi-Drug Urine Test Cup
- 80305QW, June 01, 2022, NexScreen Gen2 Multi-Drug Urine Test Dip Card

In [CR 10819](#), the attachment to the transmittal was re-organized to include a generic test system name and a statement to refer to the FDA waived analyte Internet site for HCPCS codes with more than 10 test systems listed.

Starting with [CR 12841](#), the attachment won't mention a specific test system for HCPCS codes with more than 5 test systems. The added codes in the attachment will now be mentioned in a generic manner. They are:

- 82010QW, 82962 for test systems monitoring blood glucose levels and measuring ketones in whole blood
- 80061QW, 82465QW, 83718QW, and 84478QW for test systems measuring total cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides levels in whole blood
- 82465QW and 83718QW for test systems measuring total cholesterol and HDL cholesterol in whole blood
- 83001QW
- 83036QW
- 82044QW
- 83037QW
- 83986QW for body fluid pH level, vaginal
- 84443QW
- 87077QW
- 87502QW

The tests on the first page of the [list](#) attached to CR 12841 (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 12841. They should adjust such claims you bring to their attention.

More Information

We issued [CR 12841](#) 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 4, 2022	Initial article released.

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