



New Waived Tests

MLN Matters Number: MM11354

Related Change Request (CR) Number: 11354

Related CR Release Date: July 19, 2019

Effective Date: October 1, 2019

Related CR Transmittal Number: R4336CP

Implementation Date: October 7, 2019

PROVIDER TYPES AFFECTED

This MLN Matters article is for clinical diagnostic laboratories submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11354 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify the MACs of the new tests so that they can accurately process claims. Make sure your billing staffs are aware of these CLIA-related changes.

BACKGROUND

CR 11354 presents the latest tests approved by the FDA as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for these new tests must have the modifier “QW” to be recognized as a waived test.

Note: The tests mentioned on the first page of the list attached to CR 11354 (CPT codes 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651), do not require a “QW” modifier to be recognized as a waived test.

The CPT code, effective date, and description for the latest tests approved by the FDA as waived tests under CLIA include:

- 80305QW, December 13, 2018, Shenzhen Bioeasy Biotechnology Co., Ltd, BIOEASY Multi-Drug Test Cup
- 80305QW, April 18, 2019, Mercedes Scientific Inc., Platinum+ Multi-Drug Urine Test Cup
- 80305QW, April 18, 2019, Mercedes Scientific Inc., Platinum+ Multi-Drug Urine Test Dip Card

- 87880QW, May 9, 2019, McKesson Consult Strep A Test Cassette
- 87502QW, May 28, 2019, Alere ID NOW Instrument {Nasal and Nasopharyngeal swabs}, for Influenza A/B
- 87634QW, May 29, 2019, Alere ID NOW Instrument {Nasopharyngeal swabs}, for respiratory syncytial virus

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

Note: MACs will not search their files to either retract payment or retroactively pay claims; however, MACs should adjust claims if you bring those claims to their attention.

ADDITIONAL INFORMATION

The official instruction, CR 11354, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4336CP.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
July 23, 2019	Initial article released.

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