New Waived Tests

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Related CR Release Date: September 28, 2017
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Implementation Date: October 2, 2017

Note: This article was revised on September 28, 2017, to reflect a revised CR10198. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10198 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 following approval, the Centers for Medicare & Medicaid Services (CMS) must notify the MACs of the new tests so that they can accurately process claims. CR10198 lists 17 newly added waived complexity tests.

BACKGROUND

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

This article includes the latest tests approved by the FDA as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the attached list (that is, 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:

- 87880QW, December 8, 2016, Quidel Sofia Strep A+ FIA (from throat swab only);
- 80305QW, April 28, 2017, Alere Toxicology Services Alere iCup Rx Multi-Drug Urine Test Cup;
- 87804QW, May 30, 2017, Quidel Sofia 2 {Sofia Influenza A+B FIA}; and

**Note:** MACs will not search their files to either retract payment or retroactively pay claims; however, MACs should adjust claims if they are brought to their attention.

**ADDITIONAL INFORMATION**


**DOCUMENT HISTORY**

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<td>September 28, 2017</td>
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<td>July 28, 2017</td>
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