



New Waived Tests

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Related Change Request (CR) Number: 11916

Related CR Release Date: July 24, 2020

Effective Date: October 1, 2020

Related CR Transmittal Number: R10230CP

Implementation Date: October 5, 2020

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

This article informs you 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 its MACs of the new tests so that they can accurately process claims. There are 5 newly added waived complexity tests. Make sure your billing staffs are aware of these CLIA-related changes.

BACKGROUND

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.

The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the list attached to CR 11916 (such as 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 are the following:

- 87880QW, November 26, 2019, Dealmed Medical Supplies LLC, Strep A Rapid Test Kit

- 82465QW, February 26, 2020, Germaine Laboratories Inc. AimStrip Tandem Lipid Profile and Glucose Measuring System (Germaine Laboratories Inc. AimStrip Tandem Total Cholesterol Test Strips)
- 84478QW, February 26, 2020, Germaine Laboratories Inc. AimStrip Tandem Lipid Profile and Glucose Measuring System (Germaine Laboratories Inc. AimStrip Tandem Triglycerides Test Strips)
- 86308QW, March 5, 2020, Sekisui Diagnostics, LLC. OSOM Mono Test {Whole blood}
- 87804QW, April 3, 2020, Sekisui Diagnostics, LLC, OSOM Ultra Plus Flu A&B Test {Nasal and Nasopharyngeal Swabs}

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 11916, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10230CP.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 28, 2020	Initial article released.

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