



New Waived Tests

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Related Change Request (CR) Number: 11231

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Implementation Date: July 1, 2019

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

CR 11231 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 its 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

CLIA regulations require facilities to be appropriately certified for each test performed. To make sure that CMS 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 certification level.

The latest tests approved by the FDA as waived tests under CLIA are listed below in **Table 1** and their Current Procedural Terminology (CPT) codes must have the modifier QW to be recognized as a waived test. However, the tests listed on the first page of the attachment to CR 11231 (that is, Current Procedural Terminology (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 as follows:

Table 1: New Waived Tests Requiring QW Modifier

CPT Code	Effective Date	Description
80305QW	September 14, 2018	Walmart Stores, Confirm Biosciences Equate Multi Drug of Abuse Test Cup
87880QW	October 26, 2018	BD Diagnostic Systems, BD Veritor System
89300QW	November 28, 2018	BonrayBio LensHooke X1 Semen Quality Analyzer
80305QW	November 29, 2018	Foodhold USA, LLC, CAREONE Drug Screen Tests Home Test Kit (OTC Use)
84550QW	December 11, 2018	ForaCare, Inc. FORA MD6 Uric Acid Monitoring System (ForaCare, Inc. FORA MD6 Uric Acid Test Strips)
87880QW	December 13, 2018	Easy Healthcare Corporation, Areta Strep A Swab Test
87634QW	December 18, 2018	Sekisui Inc. Silaris Dock (Silaris RSV Test)
82010QW	December 20, 2018	Apex Biotechnology Corp., KET-1 Blood Ketone Monitoring System
80305QW	January 3, 2019	Easy Healthcare Corporation, Easy@Home Single Drug Screen Test (THC)
87809QW	January 9, 2019	Quidel Corporation, QuickVue Adenoviral Conjunctivitis Test {Tear Fluid}
85018QW	February 8, 2019	HemoCue Hb 801 System
80305QW	February 13, 2019	Wondfo USA., Ltd. Q-Cup Multi-Drug Urine Test Cup

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

The official instruction, CR 11231, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4277CP.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
April 15, 2019	Initial article released.

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