



New Waived Tests

MLN Matters Number: MM10819

Related Change Request (CR) Number: 10819

Related CR Release Date: July 20, 2018

Effective Date: October 1, 2018

Related CR Transmittal Number: R4091CP

Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10819 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 contractors of the new tests so that the contractors can accurately process claims. There are 17 newly added waived complexity tests. Make sure your billing staffs are aware of these changes.

BACKGROUND

The 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.

CR10819 describes the latest tests approved by the FDA as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the new tests in the table below must have the modifier QW to be recognized as a waived test. However, the following tests do not require a QW modifier to be recognized as a waived test:

CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are shown in the following table:

CPT Code	Effective Date	Description
87502QW	March 23, 2018	Alere i System (Alere i Influenza A & B 2)
82465QW, 83718QW, 84478QW, 80061QW	April 5, 2018	ACON Laboratories Inc., Mission Lipid Panel Monitoring System (ACON Laboratories Inc., Mission Lipid Panel Test Cartridges)
85018QW	April 11, 2018	EKF-diagnostic GmbH, DiaSpect Tm System
82010QW, 82962	May 4, 2018	Vidan Diagnostics, LLC. Lucidplus Ref. No. 300300 Blood Glucose Plus β -Ketone Monitoring System
82010QW, 82962	May 8, 2018	ForaCare Inc. TD-4140 Smart Dongle Blood Glucose β -Ketone Monitoring System
80305QW	May 8, 2018	Rapid Self Test, Inc. RST Drug of Abuse Multi-Test Cup
80305QW	May 8, 2018,	Rapid Self Test, Inc. RST Drug of Abuse Multi-Test Panel
80305QW	May 11, 2018	Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Cup Tests
80305QW	May 11, 2018	Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Cup with OPI2000 Tests
80305QW	May 11, 2018	Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Dip Card Tests
80305QW	May 11, 2018	Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Dip Card with OPI2000 Tests
82274QW, G0328QW	May 18, 2018	Cen-Med Enterprises, Elite Plus Silver Immunochemical Rapid Fecal Occult Blood Test
80305QW	May 24, 2018	Premier Biotech Inc. Premier Bio-Cup
80305QW	May 24, 2018	Premier Biotech Inc. Premier Bio-Dip
80305QW	May 25, 2018	BTNX Inc. Rapid Response One Step DOA Cup MOR 300 (Urine)
80305QW	May 25, 2018	BTNX Inc. Rapid Response One Step DOA Cup MOR 2000 (Urine)
80305QW	May 25, 2018	BTNX Inc. Rapid Response Single/Multi DOA Panel MOR 300 (Urine)
80305QW	May 25, 2018	BTNX Inc. Rapid Response Single/Multi DOA Panel MOR 2000 (Urine)

In the April 2017 transmittal, CR9687 (see [MM9687](#)), the attachment accompanying the transmittal was re-organized to include a generic test system name and a statement to refer to the FDA waived analytes Internet site for those Healthcare Common Procedure Coding System (HCPCS) codes with more than 20 test systems listed. Beginning with

CR 10819, the attachment will not mention a specific test system for those HCPCS codes with more than 10 test systems. The additional codes mentioned in the attachment to CR 10819 will only be mentioned in a generic manner are 85018QW, 85610QW, and 87804QW.

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

ADDITIONAL INFORMATION

The official instruction, CR10819, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4091CP.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 20, 2018	Initial article released.

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