

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services



MLN Matters® Number: MM9687 **Revised** Related Change Request (CR) #: CR 9687

Related CR Release Date: July 15, 2016 Effective Date: October 1, 2016

Related CR Transmittal #: R3563CP Implementation Date: October 3, 2016

New Waived Tests

Note: This article was revised on July 18, 2016, to reflect the revised CR9687 issued on July 15. 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 Types Affected

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

Provider Action Needed

CR9678 informs MACs about the changes in the 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 to allow them to accurately process claims.

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. 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 that the Centers for Medicare & Medicaid (CMS) considers to be laboratory tests under CLIA (and thus requiring certification) change each year. Make sure your billing staffs are aware of these changes.

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Background

Listed below are the latest tests approved by the FDA as waived tests under CLIA. The CPT codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the 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 following table shows the CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA:

CPT Code	Effective Date	Description
G0434QW	from August 21, 2015 to December 31, 2015	Healgen Scientific LLC, Healgen Multi-Drug Urine Test Dip Card
G0477QW	on and after January 1, 2016	Healgen Scientific LLC, Healgen Multi-Drug Urine Test Dip Card
G0477QW	March 8, 2016	Tanner Scientific Multi-Panel Drug Test Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Easy Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Split Key Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Cassette
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Dip Card
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Easy Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Split Key Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Cassette

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CPT Code	Effective Date	Description
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Dip Card
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Easy Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Split Key Cup
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Cassette
G0477QW	March 18, 2016	Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Dip Card
87338QW	March 22, 2016	Meridian Bioscience Immunocard STAT! HpSA (Stool)
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Amphetamine Dip Card
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Amphetamine Quick Cup
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Amphetamine Strip
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Amphetamine Turn-Key Split Cup
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Cocaine Dip Card
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Cocaine Quick Cup
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Cocaine Strip
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Cocaine Turn-Key Split Cup

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CPT Code	Effective Date	Description
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Morphine Dip Card
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Morphine Quick Cup
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Morphine Strip
G0477QW	March 31, 2016	Assure Tech Co., Ltd. AssureTech Morphine Turn-Key Split Cup
G0477QW	April 21, 2016	Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup Tests
G0477QW	April 21, 2016	Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup with OPI 2000 Tests

The new waived complexity code 87338QW [Qualitative or semiquantitative detection test for helicobacter pylori in stool, multiple-step method] was assigned for the detection of Helicobacter pylori antigens in stool performed using the Meridian Bioscience Immunocard STAT! HpSA (Stool) test.

Be aware that your MAC will not search their files, to either retract payment or retroactively pay claims; however they should adjust such claims that you bring to their attention.

Additional Information

The official instruction, CR 9687 issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3563CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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