

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



**MLN Matters® Number: MM9563**

**Related Change Request (CR) #: CR 9563**

**Related CR Release Date: March 18, 2016**

**Effective Date: July 1, 2016**

**Related CR Transmittal #: R3479CP**

**Implementation Date: July 5, 2016**

## New Waived Tests

### Provider Types Affected

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

### Provider Action Needed

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Change Request (CR) 9563 informs MACs of new Clinical Laboratory Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Center for Medicare & Medicaid Services (CMS) must notify its MACs of the new tests so that MACs can accurately process claims. Make sure your billing staffs are aware of these changes.

### Background

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The Clinical Laboratory Improvement Amendments of 1988 (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.

Listed in the following table are 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 (CLIA waived test). However, the CPT codes 81002, 81025, 82270,

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82272, 82962, 83026, 84830, 85013, and 85651 do not require a QW modifier to be recognized as a waived test.

<b>CPT Code</b>	<b>Effective Date</b>	<b>Description</b>
81007QW	September 25, 2015	Jant Pharmacal Corporation Accutest Uriscreeen (Bacteriuria)
G0434QW	From November 3, 2015, to December 31, 2015, and G0477QW on and after January 1, 2016	Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cassette
G0434QW	From November 3, 2015, to December 31, 2015, and G0477QW on and after January 1, 2016	Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cup
G0434QW	From November 3, 2015, to December 31, 2015, and G0477QW on and after January 1, 2016	Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) DipCard
G0434QW	From November 3, 2015, to December 31, 2015, and G0477QW on and after January 1, 2016	Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA Cup
G0434QW	From November 3, 2015, to December 31, 2015, and G0477QW on and after January 1, 2016	Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA DipCard
87631QW	December 3, 2015	Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress)
G0434QW	From December 17, 2015, to December 31, 2015, and G0477QW on and after January 1, 2016	Premier BIOTECH Premier Bio-cup & Bio-Dip

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CPT Code	Effective Date	Description
G0477QW	January 13, 2016	Medical Distribution Group Inc., Identify Diagnostics Drug Test Cards
G0477QW	January 13, 2016	Medical Distribution Group Inc., Identify Diagnostics Drug Test Cups
G0477QW	January 21, 2016	American Screening Corporation, Inc. Discover Plus Drug Test Cards
G0477QW	January 21, 2016	American Screening Corporation, Inc. Discover Plus Multi-Panel Drug Test Cups

The Healthcare Common Procedure Coding System (HCPCS) code G6040QW [Alcohol (ethanol); any specimen except breath] was discontinued on December 31, 2015. The new HCPCS code G0477 [Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service] was effective January 1, 2016.

HCPCS code G0477QW describes the waived testing previously assigned code G6040QW. All tests in the attachment to CR9563 that previously had HCPCS G6040QW are now assigned G0477QW.

The new waived complexity code 87631QW [Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus) includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets] was assigned for the detection of influenza A, influenza B and respiratory syncytial virus viral RNA by reverse transcriptase polymerase chain reaction assay performed using the Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress).

Note that MACs will not search their files to either retract payment or retroactively pay claims processed before implementation of CR9563. However, MACs will adjust such claims that you bring to their attention.

## Additional Information

The official instruction, CR9563 issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3479CP.pdf> on the CMS website.

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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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