

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



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MLN Matters® Number: MM8951

Related Change Request (CR) #: CR 8951

Related CR Release Date: December 12, 2014

Effective Date: January 1, 2015

Related CR Transmittal #: R3149CP

Implementation Date: January 5, 2015

New Waived Tests

Provider Types 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

Change Request (CR) 8951 informs MACs about the new Clinical Laboratory Improvement Amendments of 1998 (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 four newly added waived complexity tests.

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The CPT codes that the CMS considers to be laboratory tests under CLIA (and thus requiring certification) change each year. If you do not have a valid, current, CLIA certificate and submit a claim to your MAC for a Current Procedural Terminology (CPT)

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code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be impacted. Make sure that your billing staffs are aware of these 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.

Listed below are the latest tests approved by the FDA as waived tests under CLIA. CPT codes for the following new tests must have the modifier QW to be recognized as a waived test. Tests with CPT codes shown on the first page of the attachment to CR8951 (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 listed in the following table.

CPT Code	Effective Date	Description
87807QW	March 18, 2014	BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens){Includes a reader}
G0434QW	May 12, 2014	Native Diagnostics International, DrugSmart Dip Single/Multi-Panel Drug Screen Dip Card Tests
87807QW	May 30, 2014	Sofia RSV
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Strip
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Cassette
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Cup
G0434QW	June 9, 2014	Healgen THC One Step Marijuana Test Dip Card
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Strip
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Cassette
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Cup
G0434QW	June 9, 2014	Healgen mAMP One Step Methamphetamine Test Dip Card
87880QW	June 11, 2014	Poly stat Strep A Strip Test {Specimen type (Throat Swab)}

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CPT Code	Effective Date	Description
87880QW	June 25, 2014	StrepAim {Specimen type (Throat Swab)}
G0434QW	June 27, 2014	Wal-Mart Stores, Inc. ReliOn Home Drug Urine Cup Test
86308QW	July 7, 2014	Jant Pharmacal Corp. Accutest Rapid Mono Test {Whole Blood}
87880QW	July 9, 2014	Cardinal Health Strep A Dipstick – Rapid Test (Throat Swab Specimen)
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Strip
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Cassette
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Cup
G0434QW	July 18, 2014	Healgen COC One Step Cocaine Test Dip Card
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Strip
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Cassette
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Cup
G0434QW	July 18, 2014	Healgen MOP One Step Morphine Test Dip Card
81003QW	August 8, 2014	Medline 120 Urine Analyzer

MACs will not search their files to either retract payment or retroactively pay claims processed prior to implementation of CR8951; however, they should adjust claims if you bring such claims to your MAC's attention.

Additional Information

The official instruction, CR8951 issued to your MAC regarding this change is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3149CP.pdf> on the CMS website.

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-Net/work-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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