

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



Coding for ICD-10-CM: More of the Basics MLN Connects® Video - In this MLN Connects® video on [Coding for ICD-10-CM: More of the Basics](#), Sue Bowman from the American Health Information Management Association (AHIMA) and Nelly Leon-Chisen from the American Hospital Association (AHA) provide a basic introduction to ICD-10-CM coding. The objective of this video is to enhance viewers' understanding of the characteristics and unique features of ICD-10-CM, as well as similarities and differences between ICD-9-CM and ICD-10-CM. Run time: 36 minutes.

MLN Matters® Number: MM9164

Related Change Request (CR) #: CR 9164

Related CR Release Date: May 22, 2015

Effective Date: July 1, 2015

Related CR Transmittal #: R3267CP

Implementation Date: July 6, 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) 9164 informs MACs of 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) notifies the MACs of the new tests so that they can accurately process claims. There are seven (7) newly added waived complexity tests, displayed in the Background section below.

Disclaimer

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CLIA requires that, for each test it performs, a laboratory facility must be appropriately certified. The Current Procedural Terminology (CPT) codes that 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 CPT code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be affected. 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 the Medicare and Medicaid programs 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. The CPT codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of CR9164 titled, “Tests Granted Waived Status under CLIA” (that is, 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 the following:

CPT Code	Effective Date	Description
83036QW	September 23, 2014	Alere Technologies AS, Alere Afinion AS101 Analyzer
G0434QW	November 13, 2014	Native Diagnostics International DrugSmart Dip Multi-Panel Drug Screen Dip Card with OPI 2000 Tests
G0434QW	December 1, 2014	Chemton Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card Tests
G0434QW	December 1, 2014	Chemton Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card with OPI 2000 Tests
87880QW	December 17, 2014	Quidel Sofia Strep A+FIA {from throat swab only}
G0434QW	December 29, 2014	Clarity Diagnostics Multi-Panel Drug Screen Dip Card Tests
G0434QW	December 29, 2014	Clarity Diagnostics Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

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The CPT code 82055 (Alcohol (ethanol); any specimen except breath) was discontinued on December 31, 2014.

The CPT code G6040 (Alcohol (ethanol); any specimen except breath) was effective on January 1, 2015.

CPT code G6040QW will be assigned to the following tests:

- Alere Toxicology Services, iScreen Saliva Alcohol Test Strip;
- Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip;
- American Screening Corporation, Reveal Saliva Alcohol Test Strip;
- Acon Laboratories Inc. Mission Saliva Alcohol Test Strip;
- Chematics Inc. Alco-Screen Saliva Alcohol Test;
- Chematics Inc. Alco-Screen 02 Saliva Alcohol Test;
- CLIAwaived Inc. Rapid Saliva Alcohol Test;
- Express Diagnostics International, Incorporated Saliva Alcohol Test;
- Germaine Laboratories AimStrip Alcohol Saliva;
- Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip;
- OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test;
- OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test;
- STC Diagnostics Q.E.D. A150 Saliva Alcohol Test;
- STC Diagnostics Q.E.D. A350 Saliva Alcohol Test; and
- Teco Diagnostics Saliva Alcohol Test.

Additional Information

The official instruction, CR9164, issued to your MAC regarding this change, is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3267CP.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” on the CMS website.

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