DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® — Information for Medicare Fee-for-Service Health Care Professionals

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MLN Matters® Number: MM7349

Related Change Request (CR) #:7349

Related CR Release Date: April 22, 2011

Effective Date: July 1, 2011

Related CR Transmittal #: R2196CP

Implementation Date: July 5, 2011

New Waived Tests

Provider Types Affected

This article is for clinical diagnostic laboratories billing Medicare Carriers or Medicare Administrative Contractors (MACs) for laboratory tests.

Provider Action Needed

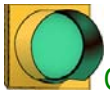
STOP – Impact to You

This change request (CR) 7349 announces two newly added 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) is notifying contractors of the new tests so that claims can be accurately processed.

CAUTION – What You Need to Know

1. On February 8, 2011, the FDA informed CMS that the Teco Diagnostics Uritek TC-101 Urine Analyzer was no longer categorized as a waived test under CLIA. This test has been removed from the list attached to CR7349.

2. On February 9, 2011, CMS determined that the code to assign to the OraSure Technologies OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is G0433 effective January 1, 2011. In addition, the code assigned to the Clearview Complete HIV 1/2 test should be G0433. Therefore, the code assigned both tests was changed from 86703QW to G0433QW in the list attached to CR7349.



GO – What You Need to Do

Make sure that your billing staffs are aware of these CLIA-related changes for 2011 and that you remain current with certification requirements.

Background

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The Current Procedural Terminology (CPT) codes that CMS consider to be laboratory tests under CLIA (and, therefore, requiring certification) change each year. CR7349, from which this article is taken, informs carriers and MACs about the latest new CPT codes that are subject to CLIA edits.

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 the list attached to CR7349 (i.e., 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.

CPT Code	Effective Date	Description
82274QW G0328QW	January 1, 2011	Polymedco Poly Stat OC-light FOB Test
87804QW	January 10, 2011	BTNX, Inc. Rapid Response Influenza A Test Cassette
87804QW	January 10, 2011	BTNX, Inc. Rapid Response Influenza B Test Cassette

Note: Medicare contractors will not search their files to either retract payment or retroactively pay claims. They will, however, adjust claims if you bring such claims to their attention.

Additional Information

The official instruction, CR7349, issued to your Medicare Carrier or MAC regarding this change may be viewed at http://www.cms.gov/Transmittals/downloads/R2196CP.pdf on the CMS website.

If you have any questions, please contact your Medicare Carrier or MAC at their toll-free number, which may be found at http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS website.