



News Flash – The revised “Clinical Laboratory Fee Schedule Fact Sheet” (January 2010), which provides general information about the Clinical Laboratory Fee Schedule, coverage of clinical laboratory services, and how payment rates are set, is now available in print format from the Centers for Medicare & Medicaid Services Medicare Learning Network. To place your order, visit <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html>, scroll down to “Related Links Inside CMS” and select “MLN Product Ordering Page.”

MLN Matters® Number: MM6906

Related Change Request (CR) #: 6906

Related CR Release Date: May 28, 2010

Effective Date: July 1, 2010

Related CR Transmittal #: R1968CP

Implementation Date: July 6, 2010

Note: This article was updated on November 30, 2012, to reflect current Web addresses. All other information remains unchanged.

New Waived Tests

Provider Types Affected

Clinical diagnostic laboratories billing Medicare Carriers or Part A/B Medicare Administrative Contractors (MACs) for laboratory tests are impacted by this change.

Provider Action Needed

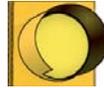


STOP – Impact to You

If you do not have a valid, current, Clinical Laboratory Improvement Amendments of 1998 (CLIA) certificate and submit a claim to your Medicare Carrier or A/B MAC for a Current Procedural Terminology (CPT) code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be impacted.

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**CAUTION – What You Need to Know**

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The CPT codes that the Centers for Medicare & Medicaid Services (CMS) consider to be laboratory tests under CLIA (and thus requiring certification) change each year. CR 6906, from which this article is taken, informs carriers and MACs about the latest new CPT codes for 2010 that are subject to CLIA edits.

**GO – What You Need to Do**

Make sure that your billing staffs are aware of these CLIA-related changes for 2010 and that you remain current with certification requirements.

Background

Listed below are the latest tests approved by the Food and Drug Administration as waived tests under CLIA. The tests are valid as soon as they are approved. The CPT codes for the following new tests MUST have the modifier QW to be recognized as a waived test.

CPT Code	Effective Date	Description
82465QW, 83718QW, 84478QW, 80061QW, 82947QW, 82950QW, 82951QW, 82952QW	December 2, 2009	Infopia USA LipidPro lipid profile and glucose measuring system
82465QW, 83718QW, 84478QW, 80061QW	December 2, 2009	Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)
G0430QW	January 1, 2010	American Screening Corporation One Screen Drug Test Cards
G0430QW	January 1, 2010	American Screening Corporation One Screen Drug Test Cups
G0430QW	January 1, 2010	Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards
G0430QW	January 1, 2010	UCP Biosciences, Inc., UCP Home Drug Screening Test Cards
G0431QW	January 1, 2010	Phamatech QuickScreen One Step Amphetamine Test

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CPT Code	Effective Date	Description
G0431QW	January 1, 2010	Phamatech QuickScreen One Step THC Screening Test
86308QW	January 4, 2010	Acceava Mono Cassette {For whole blood}
81003QW, 82044QW, 82570QW, 84703QW	January 4, 2010	Siemens, Clinitek Status+ Analyzer
81003QW, 82044QW, 82570QW, 84703QW	January 4, 2010	Siemens, Clinitek Status Connect System
82274QW, G0328QW	January 26, 2010	Care Diagnostics Clarity IFOB Test

Other Key Points of CR 6906:

- Only the following tests (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.
- Medicare carriers and MACs will not search their files to adjust claims affected by this change, but processed prior to the implementation of CR 6906. They will, however, adjust such claims that you bring to their attention.

Reminder Items from CR 6852

Note that CR 6852 [Clinical Laboratory Fee Schedule (CLFS) - Special Instructions for Specific Test Codes (CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, and G0431QW)], provided special instructions for the proper use of CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, G0431, and G0431QW as of April 1, 2010. The MLN Matters® article related to CR 6852 is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6852.pdf> on the CMS website.

CR 6852 also mentioned the following:

- If a laboratory with a CLIA certificate of waiver performs a qualitative drug screening test for multiple drug classes using a non-chromatographic method, then the test code G0430QW would be the appropriate code to bill;
- The test code G0431 is a direct replacement for CPT Code 80101;
- Clinical laboratories with a CLIA certificate of waiver should utilize new test code G0431QW; and
- Effective July 1, 2010, CPT Code 80101 will no longer be covered by Medicare, and CPT Code 80101QW was deleted on April 1, 2010.

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Additional Information

To see the official instruction (CR6906) issued to your Medicare Carrier and/or MAC, see <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1968CP.pdf> on the CMS website.

If you have questions, please contact your Medicare Carrier and/or MAC at their toll-free number which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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