DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

REVISED products from the Medicare Learning Network® (MLN)
"Communicating With Your Medicare Patients" Fact Sheet (ICN 908063) hard copy

MLN Matters® Number: MM8705 **Related Change Request (CR) #: CR 8705**

Related CR Release Date: April 4, 2014 **Effective Date: July 1, 2014**

Related CR Transmittal #: R2919CP **Implementation Date: July 7, 2014**

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 to Medicare beneficiaries.

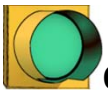
Provider Action Needed


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 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.

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) considers to be laboratory tests under CLIA (and thus requiring certification) change each year. CR 8705, from which this article is taken, informs MACs about the latest new CPT codes 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 2014 and that you remain current with certification requirements.

Background

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The Current Procedural Terminology (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 CR8705 (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
87880QW	July 29, 2013	Poly stat Strep A Flip Test
G0434QW	August 1, 2013	Alere iScreen DX Multi-Drugs of Abuse Dip Test
G0434QW	September 10, 2013	Alere iScreen DX Single Dip Card {The Alere iScreen DX Single Dip Card may include a maximum of four drugs in any combination of the 13 claimed drugs}
85018QW	December 12, 2013	Alere HemoPoint H2 System
87804QW	December 13, 2013	Sofia Analyzer and Influenza A+B FIA
G0434QW	February 21, 2014	Ultimate Analysis Cup Inc. UA Cups Test Cards
G0434QW	February 21, 2014	Ultimate Analysis Cup Inc. UA Cups
83516QW	February 27, 2014	Rapid Pathogen Screening, Inc. InflammaDry

The new CPT code 83516QW has been assigned for the immunoassay test for the visual, qualitative detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye performed using the Rapid Pathogen Screening, Inc. InflammaDry.

MACs will not search their files to either retract payment or retroactively pay claims based on the above changes; however, they will adjust claims impacted by these changes if you bring such claims to your MAC's attention.

Additional Information

The official instruction, CR 8705 issued to your MAC regarding this change is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2919CP.pdf** on the CMS website.

If you have any questions, please contact your MAC at their toll-free number, which is available at **http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html** on the CMS website.