

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



MLN Matters® Number: MM 9515

Related Change Request (CR) #: CR 9515

Related CR Release Date: January 15, 2016

Effective Date: April 1, 2016

Related CR Transmittal #: R3440CP

Implementation Date: April 4, 2016

New Waived Tests

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratory providers submitting clinical diagnostic laboratory claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

The Clinical Laboratory Improvement Amendments of 1988 (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.

The Current Procedural Terminology (CPT) codes that the Centers for Medicare & Medicaid Services (CMS) consider to be laboratory tests under CLIA (and thus requiring certification) change each year. Change Request (CR) 9515 informs the MACs about the latest new CPT codes that are subject to CLIA edits. Make sure your billing staffs are aware of the latest CLIA-related changes.

Background

Listed below are the latest tests approved by the Food and Drug Administration (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 with CPT codes 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651 do not require a QW

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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:

- 83036QW, August 10, 2015, PTS Diagnostics A1C + Professional Use;
- 82274QW, G0328QW, September 14, 2015, Tanner Scientific iFOB One Step Rapid Test;
- 87502QW, September 18, 2015, Roche Molecular, cobas Liat System (cobas Liat Influenza A/B Assay);
- G0434QW [from October 27, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test Cup;
- G0434QW [from October 27, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test DipCard;
- G0434QW [from November 10, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Cup Test;
- G0434QW [from November 10, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Dip Card Test;
- G0434QW [from November 10, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], W.H.P.M., Inc. First Sign® Drug of Abuse Morphine Dip Card Test;
- G0434QW [from November 13, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], UCP Biosciences, Inc. U-Cup Drug Test Cards;
- G0434QW [from November 13, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], UCP Biosciences, Inc. U-Card Drug Test Cups; and
- G0434QW [from December 14, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Tanner Scientific, Platinum Line® Multi-Panel Drug Test Cup.

The HCPS code G0434 [Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter] was discontinued on 12/31/2015. The new HCPCS code G0477 [Drug tests(s), presumptive, any

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number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service] was effective 1/1/2016. HCPCS code G0477QW describes the waived testing previously assigned code G0434QW. All tests in the attachment to CR9515 that previously had HCPCS G0434QW are now assigned G0477QW.

You should be aware that your MAC will not search their files, to either retract payment or retroactively pay claims; however, they should adjust such claims that you bring to their attention.

Additional Information

The official instruction, CR 9515 issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3440CP.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-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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