

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



MLN Matters® Number: MM9797

Related Change Request (CR) #: CR 9797

Related CR Release Date: November 23, 2016

Effective Date: January 1, 2017

Related CR Transmittal #: R3666CP

Implementation Date: January 3, 2017

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) 9797 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (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) must notify the MACs of the new tests so that they can accurately process claims. Make sure that your billing staffs are aware of these CLIA-related changes.

Background

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and 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.

Listed below are the latest tests approved by the 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 CR9797 (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.

Disclaimer

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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
G0477QW	February 12, 2016	Greenbrier International, Inc. Assured THC One Step Marijuana Test Cassette
G0477QW	February 12, 2016	Greenbrier International, Inc. Assured THC One Step Marijuana Test Strip
G0477QW	March 18, 2016	Safecare Biotech Urine Test Amphetamine Cassette
G0477QW	March 18, 2016	Safecare Biotech Urine Test Amphetamine Cup
G0477QW	March 18, 2016	Safecare Biotech Urine Test Amphetamine DipCard
G0477QW	March 18, 2016	Safecare Biotech Urine Test Cocaine Cassette
G0477QW	March 18, 2016	Safecare Biotech Urine Test Cocaine
G0477QW	March 18, 2016	Safecare Biotech Urine Test Cocaine DipCard
G0477QW	March 18, 2016	Safecare Biotech Urine Test Marijuana Cassette
G0477QW	March 18, 2016	Safecare Biotech Urine Test Marijuana Cup
G0477QW	March 18, 2016	Safecare Biotech Urine Test Marijuana DipCard
83986QW	May 13, 2016	Teco Diagnostics OBGYN-VpH Vaginal pH Screening Kit
G0477QW	June 9, 2016	Native Diagnostics International DrugSmart Multi-Panel Drug Screen Cup Tests
G0477QW	June 9, 2016	Native Diagnostics International DrugSmart Multi-Panel Drug Screen Cup with OPI 2000 Tests
G0477QW	June 9, 2016	Native Diagnostics International DrugSmart Dip Multi-Panel Drug Screen Dip Card Tests
G0477QW	June 9, 2016	On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Cup Tests
G0477QW	June 9, 2016	On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Cup with OPI 2000 Tests
G0477QW	June 9, 2016	On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Dip Card Tests
G0477QW	June 9, 2016	On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

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CPT Code	Effective Date	Description
G0447QW	June 9, 2016	Alfa Scientific Designs, Inc. Instant-View Multi-Drug Urine Test Cup
G0477QW	June 9, 2016	Alfa Scientific Designs, Inc. Instant-View Multi-Drug Urine Test Panel
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Marijuana Dip Card Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Marijuana Quick Cup Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Marijuana Strip Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Marijuana Turn-Key Split Cup Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Methamphetamine Dip Card
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Methamphetamine Quick Cup Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Methamphetamine Strip Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Methamphetamine Turn-Key Split Cup
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Phencyclidine Dip Card Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Phencyclidine Quick Cup Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Phencyclidine Strip Test
G0477QW	July 18, 2016	Assure Tech. Co., Ltd. AssureTech Phencyclidine Turn-Key Split Cup Test
87631QW	July 25, 2016	Roche Molecular, cobas Liat System cobas Liat Influenza A/B & RSV Assay
G0477QW	July 28, 2016	Germaine Laboratories, Inc., AimScreen Multi-Drug Urine Test DipDevice
G0477QW	July 28, 2016	Germaine Laboratories, Inc., SafeCup II Multi-Drug Urine Test Cup
G0477QW	July 29, 2016	NexScreen LLC, NEXSCREEN Multi-Drug Urine Test Cup
G0477QW	July 29, 2016	NexScreen LLC, NEXSCREEN Multi-Drug Urine Test Dip Card

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CPT Code	Effective Date	Description
86308QW	August 4, 2016	McKesson Consult Mononucleosis Test Cassette {whole blood}
87880QW	September 4, 2016	Princeton BioMeditech StatusFirst Strep A

Additional Information

The official instruction, CR9797, issued to your MAC regarding this change, is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3666CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

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