



New Waived Tests

MLN Matters Number: MM11747

Related Change Request (CR) Number: 11747

Related CR Release Date: April 17, 2020

Effective Date: July 1, 2020

Related CR Transmittal Number: R10048CP

Implementation Date: July 6, 2020

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR 11747 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 its MACs of the new tests so that they can accurately process claims. Make sure your billing staffs are aware of these newly added waived complexity tests.

BACKGROUND

The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test.

Note: The tests mentioned on the first page of the list attached to CR 11747 (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.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

- 80305QW, May 31, 2019, BTNX, Inc. Rapid Response Drug Screening Test Cup-OTC (Urine)
- 80305QW, May 31, 2019, BTNX, Inc. Rapid Response Drug Screening Test Panel-OTC (Urine)
- 80305QW, May 31, 2019, BTNX, Inc. Rapid Response Drug Screening Test Strip-OTC (Urine)
- 80305QW, June 28, 2019, BTNX, Inc. Rapid Response Drug Screening Panel
- 80305QW, June 28, 2019, BTNX, Inc. Rapid Response Drug Screening Cup

- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite Drug Test Cup
- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite Buprenorphine Drug Test Cup
- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite Butalbital Drug Test Cup
- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite EDDP Cup Test
- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite MDMA Drug Test Cup
- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite Morphine Drug Test Cup
- 80305QW, July 2, 2019, Clinical Reference Laboratory CRLstat Onsite Nortriptyline Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite Buprenorphine Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite Butalbital Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite EDDP Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite MDMA Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite Morphine Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck NxStep Onsite Nortriptyline Drug Test Cup
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck Dip Drug Test
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck Buprenorphine Dip Drug Test
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck Butalbital Dip Drug Test
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck EDDP Dip Drug Test
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck MDMA Dip Drug Test
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck Morphine Dip Drug Test
- 80305QW, July 2, 2019, Express Diagnostics International, Inc., DrugCheck Nortriptyline Dip Drug Test
- 80305QW, July 2, 2019, Zero Chaos, zerochaos Drug Test Cup
- 80305QW, July 2, 2019, Zero Chaos, zerochaos Buprenorphine Drug Test Cup
- 80305QW, July 2, 2019, Zero Chaos, zerochaos Butalbital Drug Test Cup

- 80305QW, July 2, 2019, Zero Chaos, zerochaos EDDP Drug Test Cup
- 80305QW, July 2, 2019, Zero Chaos, zerochaos MDMA Drug Test Cup
- 80305QW, July 2, 2019, Zero Chaos, zerochaos Morphine Drug Test Cup
- 80305QW, July 2, 2019, Zero Chaos, zerochaos Nortriptyline DrugTest Cup
- 80061QW, 82465QW, 82962, 83718QW, 84478QW, July 3, 2019, KPI Healthcare Co., Ltd. CURO L5 Lipid Profile and Glucose Measuring System
- 80305QW, July 11, 2019, Xiamen USEFUL Imp and Exp CO., LTD. Diagnostic Test One Step Rapid Test Cup
- 80305QW, July 11, 2019, Xiamen USEFUL Imp and Exp CO., LTD. Diagnostic Test One Step Rapid Test DipCard
- 80305QW, July 17, 2019, Medical Disposables, MD Drug Screen MD Quick Cup Tests (MOR300)
- 80305QW, July 17, 2019, Medical Disposables, MD Drug Screen MD Quick Cup Tests (MOR2000)
- 80305QW, August 19, 2019, Micro Distributing II, LTD. STAT Cup One Step Drug Test
- 87807QW, August 28, 2019, Abbott Diagnostics Scarborough Inc., BinaxNow RSV Card (For NP Swabs and NP Wash Specimens)
- 82044QW, 82570QW, August 30, 2019, Jant Pharmacal Accutest M2 Microalbumin Urine Reagent Strips
- 80305QW, September 17, 2019, Easy Healthcare Corporations, Areta Multi-Drug Test Cup (MOR 300)
- 80305QW, September 17, 2019, Easy Healthcare Corporations, Areta Multi-Drug Test Cup (MOR 2000)
- 80305QW, September 17, 2019, Easy Healthcare Corporations, Areta Multi-Drug Screen Test (MOR 300)
- 80305QW, September 17, 2019, Easy Healthcare Corporations, Areta Multi-Drug Screen Test (MOR 2000)
- 80305QW, September 18, 2019, Clarity Diagnostics Multi-Drug Home Rapid Test Cup (Urine)
- 80305QW, September 18, 2019, Clarity Diagnostics Multi-Drug Home Rapid Test Panel (Urine)
- 80305QW, September 26, 2019, Premier Biotech, Inc., Premier Biotech Multi-panel Drug Screen Cup Tests
- 80305QW, September 26, 2019, Premier Biotech, Inc., Premier Biotech Multi-panel Drug Screen Cup with OPI 2000 Tests
- 80305QW, September 26, 2019, Premier Biotech, Inc., Premier Biotech Multi-panel Drug Screen Dip Card Tests
- 80305QW, September 26, 2019, Premier Biotech, Inc., Premier Biotech Multi-panel Drug Screen Dip Card with OPI 2000 Tests
- 80305QW, September 26, 2019, Healgen Scientific, Helagen Accurate Multi Drug Urine Test Cup
- 87502QW, September 30, 2019, Cepheid GeneXpert Xpress System (Xpert Xpress Flu Assay) (GeneXpert Xpress IV hub configuration)

- 87631QW, September 30, 2019, Cepheid GeneXpert Xpress System (Xpert Xpress Flu/RSV Assay) (GeneXpert Xpress IV hub configuration)
- 80305QW, October 1, 2019, Tanner Scientific Inc., BluRapids Multi-Drug Urine Test Cup
- 87651QW, October 18, 2019, Cepheid GeneXpert Xpress System (Xpert Xpress Strep A) (GeneXpert Xpress IV hub configuration)
- 82010QW, October 24, 2019, AmVenturex, Inc., KetoCoach Blood Ketone Monitoring System
- 80305QW, November 26, 2019, Premier Biotech, Inc., Salvia Alcohol Test
- 80305QW, December 16, 2019, Confirm Bioscience, DrugConfirm Multi-Drug Urine Test Cup
- 80305QW, December 16, 2019, Confirm Bioscience, DrugConfirm Multi-Drug Urine Test DipCard
- 80305QW, December 19, 2019, Confirm Bioscience, DrugConfirm Multi-Drug Urine Test Cup II
- 80305QW, December 19, 2019, Confirm Bioscience, DrugConfirm Multi-Drug Urine Test Dip Card II
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test (Buprenorphine)
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test (Butalbital)
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test (EDDP)
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test (MDMA)
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test (Morphine)
- 80305QW, January 6, 2020, Origin Diagnostics Origin Instant Drug Test (Nortriptyline)

The October 2018 transmittal, CR 10819, mentioned the attachment accompanying the transmittal was re-organized to include a generic test system name and a statement to refer to the FDA waived analyte Internet site for those HCPCS codes with more than 10 test systems listed. For 87807QW, more than 10 test systems have been mentioned and only a generic test system will be listed in the attachment. You can find the associated MLN Matters Article at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10819.pdf>

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.

Note: MACs will not search their files to either retract payment or retroactively pay claims; however, MACs should adjust claims if you bring those claims to their attention.

ADDITIONAL INFORMATION

The official instruction, CR 11747, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10048CP.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
April 17, 2020	Initial article released.

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