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New Waived Tests

MLN Matters Number: MM11080
Related Change Request (CR) Number: 11080
Related CR Release Date: January 11, 2019
Effective Date: April 1, 2019
Related CR Transmittal Number: R4195CP
Implementation Date: April 1, 2019

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

CR11080 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 CLIA-related changes.

BACKGROUND

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that CMS only pays for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, Medicare edits laboratory claims at the CLIA certificate level. However, the tests mentioned on the first page of the list attached to CR11080 (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 latest tests approved by the FDA as waived tests under CLIA are listed below. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW 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 as follows:

- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Panel Dip M300
- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Panel Dip M2000

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- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Quick Cup M300
- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Quick Cup M2000
- 86618QW, August 30, 2018, Quidel Sofia 2 {Fingerstick whole blood}
- 80305QW, October 2, 2018, McKesson Medical-Surgical, Mckesson Drugs of abuse PPX Test Cup
- 80305QW, October 4, 2018, Jant Pharmacal Corp. Accutest VALUPAK Drug Screen Cup
- 80305QW, October 9, 2018, McKesson Medical-Surgical Inc. McKesson Multi Panel Drugs of abuse Test Cup
- 83036QW, October 23, 2018, Alere Technologies AS, AS100 Analyzer
- 83036QW, October 23, 2018, Alere Technologies AS, Afinion 2 Analyzer
- 80305QW, November 2, 2018, American Screening LLC, Precision Plus Quick Cup Tests
  80305QW, November 2, 2018, American Screening LLC, Precision DX Quick Cup Tests
- 87804QW, November 21, 2018, Polymedco Inc., Poly stat Flu A&B {for use with nasal and nasophayngeal swabs}
- 87634QW, November 23, 2018, Mesa Biotech Accula (Accula RSV Test)

ADDITIONAL INFORMATION

The official instruction, CR11080, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4195CP.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
January 11, 2019	Initial article released.

license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com

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