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New Waived Tests

MLN Matters Number: MM10586
Related Change Request (CR) Number: 10586
Related CR Release Date: April 6, 2018
Effective Date: July 1, 2018
Related CR Transmittal Number: R4018CP
Implementation Date: July 2, 2018

PROVIDER TYPE 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) 10586 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 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 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.

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 CR10586 (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.

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

- 80305QW, December 7, 2017, Jant Pharmacal Corporation Accutest Value+Multi-Drug Urine Test Cup
- 87502QW, December 19, 2017, Cepheid Gene Xpert Xpress System (Xpert Flu Xpress)

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- 87880QW, December 21, 2017, Quidel Sofia 2 (Sofia StrepA+FIA){from throat swab only}
- 82044QW, 82570QW, January 11, 2018, Medline Industries, Inc., Medline 120 Mini Analyzer Test System (Medline Industries, Inc. Medline Urinalysis Reagent Strips)
- 80061QW, 82465QW, 83718QW, 84478QW, January 19, 2018, ACON Laboratories Inc., Mission Cholesterol Pro Monitoring System (Mission Cholesterol Pro Test Cartridges)
- G0433QW, January 30, 2018, bioLytical Laboratories, INSTI HIV-1/HIV-2 Antibody Test {Fingerstick whole blood}

The attachment to CR10586 contains the test name, manufacturer, and use for each of the above listed CPT codes. You should be aware that MACs will not search their files to either retract payment or retroactively pay claims. However, they should adjust claims that you bring to their attention.

ADDITIONAL INFORMATION

The official instruction, CR10586, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4018CP.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/.

DOCUMENT HISTORY

Date of Change	Description
April 6, 2018	Initial article released.

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