



New Waived Tests

MLN Matters Number: MM10321

Related Change Request (CR) Number: 10321

Related CR Release Date: November 3, 2017 Effective Date: January 1, 2018

Related CR Transmittal Number: R3902CP Implementation Date: January 2, 2018

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) 10321 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 updates.

BACKGROUND

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

CR 10321 describes the latest tests approved by the FDA as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the 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 found in the attachment CR10321 (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 include:

- 87807QW, June 30, 2017, Quidel Sofia 2 {Sofia RSV FIA}

- 82274QW, G0328QW, June 5, 2017, Henry Schein OneStep Pro+FIT (1)
- 80305QW, August 10, 2017, CLIAwaived Inc. Instant Drug Test Cup/Card II (IDTC II)
- 80305QW, September 5, 2017, Premier Biotech Inc., Premier UTox Cup
- 87804QW, September 7, 2017, McKesson Consult Influenza A & B {Nasal and Nasopharyngeal Swabs}
- 87804QW, September 8, 2017, PBM Princeton Biomedical Corp. ImmunoCard STAT! Flu A&B {Nasal and Nasopharyngeal Swabs}.

The attachment to CR10321 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, CR10321, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3902CP.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
November 3, 2017	Initial article released.

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