



New Waived Tests

MLN Matters Number: MM10958 **Revised**

Related Change Request (CR) Number: 10958

Related CR Release Date: November 15, 2018

Effective Date: January 1, 2019

Related CR Transmittal Number: R4169CP

Implementation Date: January 7, 2019

Note: This was revised on November 16, 2018, to reflect a revised CR10958 issued on November 15. The CR was revised to correct the description of CPT code 81003QW. Also, the CR release date, transmittal number, and the Web address for accessing the CR were revised. All other information remains the same.

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) 10958 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 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 CR10958 (namely, 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 as follows:

- 80305QW, March 8, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test Cups
- 80305QW, March 8, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test DipCards
- 87651QW, May 2, 2018, Alere i Instrument (Alere i Strep A 2)
- 82274QW, G0328QW, May 4, 2018, McKesson Consult Immunochemical Fecal Occult Blood Test
- 80305QW, May 15, 2018, MyDrugTestCups.com, MyDrugTest Multi-Drug Urine Test Cup
- 80305QW, May 15, 2018, MyDrugTestCups.com, MyDrugTest Multi-Drug Urine Test Dip Card
- 80305QW, May 16, 2018, Confirm BioSciences, Smart Choice Multi Panel DOA Test Cup
- 80305QW, May 16, 2018, Confirm BioSciences, Smart Choice Multi Panel DOA Test Dip Card;
- 82044QW, 82570QW, June 14,2018, BTNX, Inc., Rapid Response U120S Urine Analyzer Test System (BTNX, Inc. Rapid Response Urinalysis Reagent Strips (Microalbumin/Creatinine))
- 80305QW, July 16, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test Cups
- 80305QW, July 16, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test Dip Card
- 81003QW, July 27, 2018, BTNX, Inc., Rapid Response **U120S** Urine Analyzer Test System
- 80305QW, July 30, 2018, Hangzhou Clongene Biotech Co., Ltd. Clungene Multi-Drug Test Easy Cup
- 80305QW, July 30, 2018, Hangzhou Clongene Biotech Co., Ltd. Clungene Multi-Drug Test Dip Card
- 87502QW, August 10, 2018, Mesa Biotech Accula (Accula Flu A/Flu B test)
- 87502QW, August 10, 2018, Sekisui Inc., Silaris Dock (Silaris Influenza A&B Test)

Note: 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, CR10958, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4169CP.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
November 16, 2018	The article was revised to reflect a revised CR10958 issued on November 15. The CR was revised to correct the description of CPT code 81003QW. Also, the CR release date, transmittal number, and the Web address for accessing the CR were revised. All other information remains the same.
September 21, 2018	Initial article released.

Disclaimer: This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2017 American Medical Association. All rights reserved.

Copyright © 2018, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To 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

The American Hospital Association (the "AHA") has not reviewed, and is not responsible for, the completeness or accuracy of any information contained in this material, nor was the AHA or any of its affiliates, involved in the preparation of this material, or the analysis of information provided in the material. The views and/or positions presented in the material do not necessarily represent the views of the AHA. CMS and its products and services are not endorsed by the AHA or any of its affiliates.