



New Waived Tests

MLN Matters Number: MM12381

Related Change Request (CR) Number: 12381

Related CR Release Date: August 6, 2021

Effective Date: October 1, 2021

Related CR Transmittal Number: R10897CP

Implementation Date: October 4, 2021

Provider Types Affected

This MLN Matters Article is for providers billing Medicare Administrative Contractors (MACs) for Clinical Laboratory Improvement Amendments (CLIA) waived laboratory tests they provide to Medicare patients.

Provider Action Needed

Make sure your billing staff is aware of these changes.

Background

The [Clinical Laboratory Improvement Amendments of 1988](#) (CLIA) regulations require a facility to be appropriately certified for each test it performs. CMS edits laboratory claims at the CLIA certificate level to make sure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver.

Listed below are the latest tests the FDA approved as waived tests under CLIA. The CPT codes for the following new tests must have the modifier QW to be recognized as a waived test.

CPT Code	Effective Date	Description
80305QW	October 9, 2020	American Screening LLC Discover Panel Dip Card Tests MOR 2000
80305QW	October 9, 2020	American Screening LLC OneScreen Plus Panel Dip Card Tests MOR300
80305QW	October 9, 2020	American Screening LLC OneScreen Plus Panel Dip Card Tests MOR2000
80305QW	October 9, 2020	American Screening LLC Reveal Panel Dip Card Tests MOR300
80305QW	May 3, 2021	Lendas UAB EXPLORO Highly Sensitive THC test
80305QW	May 5, 2021	Clinical Reference Laboratory CRLStat Multi-Drug Urine Test Cup

More Information

We issued [CR 12381](#) to your MAC as the official instruction for this change. We've attached the complete list of Tests Granted Waived Status Under CLIA to this CR.

For more information, contact your [MAC](#).

Document History

Date of Change	Description
August 9, 2021	Initial article released.

Disclaimer: Paid for by the Department of Health & Human Services. 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 2020 American Medical Association. All rights reserved.

Copyright © 2013-2021, the American Hospital Association, Chicago, Illinois. Reproduced by CMS 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. 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.