New Waived Tests

MLN Matters Number: MM10418
Related Change Request (CR) Number: 10418
Related CR Release Date: January 5, 2018
Effective Date: April 1, 2018
Related CR Transmittal Number: R3945CP
Implementation Date: April 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) 10418 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. 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. There are four (4) newly added waived complexity tests. Make sure your billing staffs are aware of these changes.

BACKGROUND

The Clinical Laboratory Improvement Amendments of 1988 (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.

CR10418 describes the latest tests approved by the Food and Drug Administration (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 CR10418 (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 as follows:
The new waived complexity code 85025QW [Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count] was assigned for the detection of hematocrit, hemoglobin, platelet count, red blood cell count, white blood cell count and white blood cell differential performed using the Sysmex XW-100.

The new code 87634 [Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique] was effective 1/1/2018. HCPCS code 87634QW describes the waived testing previously assigned to the code 87801QW. The HCPCS code for the Alere i System Respiratory Syncytial Virus is now assigned the HCPCS code 87634QW.

**ADDITIONAL INFORMATION**


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**

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>January 5, 2018</td>
<td>Initial article released</td>
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