



Related MLN Matters Article #: MM6021

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Clinical Laboratory Fee Schedule - New Waived Tests

Key Words

MM6021, CR6021, R1527CP, Clinical, Laboratory, Schedule, Waived

Provider Types Affected

Clinical diagnostic laboratories that bill Medicare Carriers or Part A/B Medicare Administrative Contractors (A/B MACs) for laboratory tests

Key Points

- The effective date of the instruction is July 1, 2008.
- The implementation date is July 7, 2008.
- Change Request (CR) 6021 announces the latest tests that the Food and Drug Administration has approved (effective July 1, 2008) as **waived tests** under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- In order for a CLIA-enrolled waived laboratory to bill for these tests, the assigned Current Procedural Terminology (CPT) codes must contain the QW modifier.
- The new waived tests, CPT codes, and effective dates for each are provided in Table 1 on pages 2 and 3 of MLN Matters article MM6021.
- Medicare Carriers and A/B MACS will not search their files to either retract payment or retroactively pay claims processed prior to implementation of CR6021, but they will adjust such claims that are brought to their attention.

Background

- CLIA regulations require that a laboratory facility be appropriately certified for each test that it performs. Further, these regulations require facilities with a Certificate of Waiver to perform only CLIA waived tests
- To ensure that Medicare only pays laboratories with a CLIA certificate of waiver for tests that are approved as waived complexity under the Clinical Laboratory Fee Schedule, laboratory claims are currently edited at the CLIA certificate level.

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Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6021.pdf> on the CMS website.

The official instruction (CR6021) regarding this change may be viewed at

<http://www.cms.hhs.gov/Transmittals/downloads/R1527CP.pdf> on the CMS website.