



New Waived Tests – JA6179

Related CR Release Date : September 12, 2008

Date Job Aid Revised: October 2, 2008

Effective Date: October 1, 2008

Implementation Date: October 6, 2008

Key Words	MM6179, CR6179, R1594CP, Waived, Test
Contractors Affected	<ul style="list-style-type: none"> • Medicare Carriers • Part A/B Medicare Administrative Contractors (A/B MACs)
Provider Types Affected	Clinical laboratories and providers that submit claims to Medicare Carriers and/or A/B MACs for services provided to Medicare beneficiaries



Change request (CR) 6179 announces the new waived tests approved by the Food and Drug Administration (FDA) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Provider Needs to Know...

- New waived tests are approved by the FDA on a flow basis. The tests are valid as soon as they are approved. The new waived tests announced by CR6179 (and their effective dates) can be found in the table on page 2 of MLN Matters article MM6179.
- The new waived Current Procedural Terminology (CPT) / Healthcare Common Procedure Coding System (HCPCS) code 87809 has been assigned to the infectious agent antigen detection by immunoassay with direct optical observation; adenovirus.
- The HCPCS code assigned to the Rapid Pathogen Screening PRS Adeno Detector test has been changed to 87809QW with an effective date of January 1, 2008.
- The new waived CPT code, 83520QW has been assigned for the albumin test performed using the A HemoCue Albumin 201 System with an effective date of June 13, 2008.

- As of May 1, 2008, the following test systems are either discontinued or are no longer manufactured, and their names have been removed from the list of tests granted waived status under CLIA:
 - Metrika A1c Now for Prescription Home Use (K020234),
 - Metrika A1c Now™ - Professional Use (K000887),
 - Metrika A1c Now for Professional Use (K020235),
 - Metrika DRx® HbA1c (Professional Use Test System),
 - Bayer DCA 2000 – glycosylated hemoglobin (Hgb A1c), and
 - Bayer DCA 2000+ - glycosylated hemoglobin (Hgb A1c).
- The Bayer A1CNow+ {For Professional Use} was granted waived complexity categorization because of its home (over the counter) use. Effective May 1, 2008, the CPT code for Bayer A1CNow+ {For Professional Use} test system has been changed from 83036QW to 83037QW on the list of tests granted waived status under CLIA.
- The attachment to CR6179 includes the list of tests granted waived status under CLIA.

Note: The tests mentioned on the first page of the attachment (i.e., CPT codes: 81002, 81025, 82270, 82272, G0394, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

Background

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that the Centers for Medicare & Medicaid Services (CMS) only pays 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.

Operational Impact

Medicare Carriers or A/B MACs will not automatically adjust claims processed prior to the implementation of these changes. However, they will adjust claims that providers bring to their attention.

Reference Materials

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6179.pdf> on the CMS website.

The official instruction (CR6179) regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1594CP.pdf> on the CMS website.