



New Waived Tests – JA6570

Related CR Release Date: August 21, 2009

Date Job Aid Revised: August 31, 2009

Effective Date: October 1, 2009

Implementation Date: October 5, 2009

Key Words MM6570, CR6570, 1799CP, Waived, Tests

Contractors Affected

- Part A/B Medicare Administrative Contractors (A/B MACs)
- Medicare Carriers

Provider Types Affected Clinical laboratories and providers that submit claims to Medicare Carriers and/or A/B MACs for laboratory test services provided to Medicare beneficiaries



Change Request (CR) 6570 alerts providers that the Centers for Medicare & Medicaid Services (CMS) has listed the fourteen latest tests approved by the Food and Drug Administration (FDA) as waived tests under Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Provider Needs to Know...

- 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.

CPT Code	Effective Date	Description
82274QW G0328QW	December 4, 2008	Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT)
84703QW	January 26, 2009	Siemens Clinitek Status Urine Chemistry Analyzer
82962, 82465QW	January 29, 2009	Roche Diagnostics Accutrend Plus System (fingerstick Whole blood)
82274QW G0328QW	March 5, 2009	Henry Schein One Step+ iFOBT
81003QW, 82044QW, 82570QW	March 5, 2009	Siemens Clinitek Status Urine Chemistry Analyzer
87804QW	March 10, 2009	EarlyDetect Pro Influenza A Test
87804QW	March 10, 2009	EarlyDetect Pro Influenza B Test
83986QW	March 16, 2009	Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test
86308QW	April 14, 2009	Acceava Mono II {Whole Blood}
80101QW	April 30, 2009	1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II
87880QW	May 21, 2009	Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations)
86318QW	May 21, 2009	Inverness Medical Signify H. Pylori Whole Blood
86318QW	May 21, 2009	EarlyDetect H. Pylori Whole Blood Rapid Test

- The CPT code assigned to the HemoCue Albumin 201 System has been changed from 83520QW to 82043QW with an effective date of October 1, 2009.
- The Medicare contractors will deny the use of code 83520QW submitted by facilities with a valid, current CLIA certificate of waiver for dates of service on or after October 1, 2009.
- The following CPT codes do not require a QW modifier to be recognized as a waived test: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651 (see Attachment in CR6570).

Background

- CLIA regulations require a facility to be appropriately certified for each test it performs.
- 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.

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- CMS identifies waived tests by providing an updated list of waived tests to Medicare contractors on a quarterly basis via a Recurring Update Notification.
 - To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.
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**Operational
Impact**

Medicare Carriers and A/B MACs will not search their files to adjust claims affected by this change, but processed prior to the implementation of CR6570. However, they will adjust such 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/MM6570.pdf> on the CMS website.

The official instruction (CR6570) regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1799CP.pdf> on the CMS website.
