



**News Flash - Flu Shot Reminder** - Flu Season Is Coming! It's not too early to start vaccinating as soon as you receive vaccine. Encourage your patients to get a flu shot as it is still their best defense against the influenza virus. *(Medicare provides coverage of the flu vaccine without any out-of-pocket costs to the Medicare patient. No deductible or copayment/coinsurance applies.)* And don't forget, health care workers also need to protect themselves. **Get Your Flu Shot. – Not the Flu. Remember** - Influenza vaccine plus its administration are covered Part B benefits. Note that influenza vaccine is NOT a Part D covered drug. For information about Medicare's coverage of the influenza virus vaccine and its administration as well as related educational resources for health care professions and their staff, visit [http://www.cms.hhs.gov/MLNProducts/Downloads/flu\\_products.pdf](http://www.cms.hhs.gov/MLNProducts/Downloads/flu_products.pdf) on the CMS website. To order, free of charge, a quick reference chart on Medicare Part B Immunization Billing, go to [http://cms.meridianksi.com/kc/main/kc\\_frame.asp?kc\\_ident=kc0001&loc=5](http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5) on the CMS website.

MLN Matters Number: MM6179

Related Change Request (CR) #: 6179

Related CR Release Date: September 12, 2008

Effective Date: October 1, 2008

Related CR Transmittal #: R1594CP

Implementation Date: October 6, 2008

## New Waived Tests

### Provider Types Affected

Clinical laboratories and providers that submit claims to Medicare carriers and/or Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries.

### What You Need to Know

CR 6179, from which this article is taken, informs providers, Medicare carriers, and A/B MACs of new waived tests approved by the Food and Drug Administration (FDA) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Make sure that your billing staffs are aware of these newly waived tests, which you can find listed in the table below.

### Background

#### Disclaimer

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 2007 American Medical Association.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that the Centers for Medicare & Medicaid Services (CMS) 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.

New waived tests are approved by the FDA on a flow basis, and the tests are valid as soon as they are approved. The new waived tests announced by CR 6179 (and their effective dates) are in the following table:

CPT Code*	Effective Date	Description
87880QW	June 28, 2007	PSS World Medical Select Diagnostics Strep A Twist
87880QW	March 19, 2008	Jant Pharmacal Accutest Integrated Strep A Rapid Test Device
87880QW	March 19, 2008	Inverness Medical Biostar Acceava Strep A Twist
87880QW	April 8, 2008	Diagnostic Test Group Clarity Strep A Rapid Test Strips
80061QW, 82465QW, 83718QW, 84478QW	April 14, 2008	Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)
82465QW, 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 84450QW, 84460QW	April 14, 2008	Abaxis Piccolo xpress Chemistry Analyzer {Lipid Panel Plus Reagent Disc} (Whole Blood)}
82042QW, 82150QW, 82247QW, 82977QW, 84157QW, 84075QW, 84450QW, 84460QW	April 14, 2008	Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)
89300QW	June 12, 2008	SpermCheck Vasectomy
83520QW	June 13, 2008	HemoCue Albumin 201 System

\*These new tests must have the modifier QW to be recognized as a waived test.

CR 6179 also announces that:

- The new waived CPT/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

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- 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 CR 6179 includes the list of tests granted waived status under CLIA. Please note that 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.

Please note that your Medicare carrier or MAC will not automatically adjust claims processed prior to the implementation of these changes; however they will adjust claims that you bring to their attention.

## Additional Information

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For complete details, please see the official instruction, CR6719, issued to your carrier or A/B MAC regarding this change. That instruction may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1594CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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