



News Flash - The *Clinical Laboratory Fee Schedule Fact Sheet*, which provides general information about the Clinical Laboratory Fee Schedule, coverage of clinical laboratory services, and how payment rates are set, is now available in downloadable format from the Centers for Medicare & Medicaid Services Medicare Learning Network at http://www.cms.hhs.gov/MLNProducts/downloads/clinical_lab_fee_schedule_fact_sheet.pdf on the CMS website. The *Clinical Laboratory Fee Schedule Fact Sheet*, is also available in print format. To place your order, visit <http://www.cms.hhs.gov/mlnqeninfo/>, scroll down to "Related Links Inside CMS" and select "MLN Product Ordering Page."

MLN Matters Number: MM6021

Related Change Request (CR) #: 6021

Related CR Release Date: May 30, 2008

Effective Date: July 1, 2008

Related CR Transmittal #: R1527CP

Implementation Date: July 7, 2008

Clinical Laboratory Fee Schedule - New Waived Tests

Provider Types Affected

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

What You Need to Know

CR 6021 announces the latest tests that the Food and Drug Administration (FDA) has approved (effective July 1, 2008) as waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Please be aware that In order for a laboratory with a valid, current certificate of waiver 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, below.

Make sure that your billing staffs are aware of these newly approved FDA waived tests under CLIA.

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Background

Clinical Laboratory Improvement Amendments of 1988 (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 (COW) to perform only CLIA waived tests

Note: 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 (CLFS), laboratory claims are currently edited at the CLIA certificate level.

In addition, the Centers for Medicare & Medicaid Service (CMS) is mandated by Section 1833(h) of the Social Security Act to add updated test codes to the CLFS, and CR 6021 announces the latest tests that the FDA has approved as waived tests under CLIA.

In order for a CLIA-enrolled, waived laboratory to bill for these tests, the Current Procedural Terminology (CPT) codes associated with them must contain a QW modifier. Table 1, below, lists the CPT codes, descriptions, and effective dates for these latest tests that the FDA has approved as waived tests under CLIA. Please note that the CPT codes for the tests in the table must have the modifier QW to be recognized as waived tests.

**Table 1
FDA-Approved Waived Tests under CLIA**

CPT Code	Description
80047QW dates of service on or after January 1, 2008	Basic Metabolic Panel (Calcium, Ionized)
80048QW dates of service on or after January 16, 2008	Basic Metabolic Panel, (Calcium, total)
80051QW dates of service on or after October 30, 2007	Electrolyte Panel
80053QW dates of service on or after January 16, 2008	Comprehensive Metabolic Panel
82042QW dates of service on or after October 4, 2006	Albumin; Urine or Other source, Quantitative, Each Specimen
82150QW dates of service on or October 4, 2006	Amylase
82247QW dates of service on or after October 4, 2006	Bilirubin; Total
82977QW dates of service on or after October 4, 2006	Glutamyltransferase, Gamma (GGT)

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CPT Code	Description
84075QW dates of service on or after October 4, 2006	Phosphatase, Alkaline
84157QW dates of service on or after October 4, 2006	Protein, Total, Except by Refractometry; Other Source (e.g., Synovial Fluid, Cerebrospinal Fluid)
84520QW dates of service on or after October 4, 2006	Urea Nitrogen; Quantitative
87808QW dates of service on or after January 1, 2007	Infectious Agent Antigen Detection by Immunoassay with Direct Optical Observation; Trichomonas Vaginalis
87999QW dates of service on or after July 1, 2007	Unlisted Microbiology Procedure

Be aware that carriers and A/B MACS will not search their files to either retract payment or retroactively pay claim processed prior to implementation of CR6021, but they will adjust such claims if you bring them to their attention.

Additional Information

You can find the official instruction to your carrier or A/B MAC by going to CR 6021, located at <http://www.cms.hhs.gov/Transmittals/downloads/R1527CP.pdf> on 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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