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NEWS FLASH	Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html on the CMS website.

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Implementation Date: April 2, 2007

New Waived Tests

Note: This article was updated on June 5, 2013, to reflect current Web addresses. All other information remains unchanged.

Provider Types Affected

Providers and suppliers who bill Medicare carriers or Medicare Administrative Contractors (A/B MACs) for clinical diagnostic laboratory services

Provider Action Needed

CR 5484, from which this article is taken, notifies your carriers and A/B MACs of the new Food and Drug Administration (FDA)-approved tests (effective October 4, 2006) that are waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), so that they can accurately process your claims.

Background

First, remember that CLIA regulations require a laboratory facility to be appropriately certified for each test it performs. Further, to ensure that Medicare & 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.

Some specific background about waived tests may, at this point, also be helpful. These new laboratory tests (which the FDA approves on a flow basis) are valid (and marketed) as soon as they are approved. Therefore, as soon as informed by the FDA of the test approvals, the Centers for Medicare & Medicaid Services (CMS) must immediately notify the carriers and A/B MACs so that they are ready to process claims when submitted. CR

5484, from which this article is taken, announces the latest tests approved by the FDA as waived tests under CLIA. These tests are described in the bulleted paragraph (below). Note that each of the Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test, and that these new waived tests are effective on October 4, 2006.

New FDA Waived Tests Under CLIA

- CPT/HCPCS code, 82042QW, has been assigned for the albumin test performed using the Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}.
- CPT/HCPCS code, 82150QW, has been assigned for the amylase test performed using the Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}.
- CPT/HCPCS code, 82247QW, has been assigned for the total bilirubin test performed using the Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}.
- CPT/HCPCS code, 82977QW, has been assigned for the gamma glutamlytransferase (GGT) test performed using the Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}.
- CPT/HCPCS code, 84075QW, has been assigned for the alkaline phosphatase test performed using the Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}.
- CPT/HCPCS code, 84157QW, has been assigned for the total protein test performed using the Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}.
- CPT/HCPCS code, 84520QW, has been assigned for the urea (BUN) test performed using the Arkray SPOTCHEM EZ Chemistry Analyzer.

Table 1 - Latest FDA Waived Tests Under CLIA*

CPT Code/Modifier	Effective Date	Description
84450QW and 84460QW	August 16, 2005	Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}
87899QW	March 30, 2006	Rapid Pathogen Screening RPS Adeno Detector
86308QW	July 27, 2006	PerMaxim RediScreen Mononucleosis {Whole Blood}
82274QW, G0328QW	August 3, 2006	Enterix Insure II Fecal Immunochemical Test
82274QW, G0328QW	August 9, 2006,	Teco Rapid Fecal Occult Blood (FOB) Card Test
82274QW, G0328QW	September 22, 2006	OcculTech Fecal Occult Blood Rapid Test
82042QW, 82150QW, 82247QW, 82977QW, 84075QW, and 84157QW	October 4, 2006	Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}
84520QW	October 4, 2006	Arkray SPOTCHEM EZ Chemistry

CPT Code/Modifier	Effective Date	Description
		Analyzer{whole blood} for urea (BUN)
84450QW	October 5, 2006	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood} for aspirate amminotransferase (AST)(SGOT)
85018QW	October 10, 2006	HemoCue Hb 301 System
87999QW	October 16, 2006	Genzyme Diagnostics OSOM BVBlue Test
87880QW	November 1, 2006	Inverness Medical BioStar Acceava Strep A Test
80101QW	November 14, 2006	Branan Medical Corporation, QuickTox Drug Screen Dipcard
80101QW	November 14, 2006	Branan Medical Corporation, FasTox Multiple Drug Dipcard
86308QW	November 22, 2006	LifeSign Status Mono {for whole blood}

*The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test.

In addition, it is also important that you note that the tests displayed in table 2, below, do not require a QW modifier to be recognized as a waived test.

Table 2
Waived Tests That Do Not Require the QW Modifier

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270 82272 G0394 (Contact your Medicare carrier for claims instructions.)	Fecal occult blood	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
82962	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	Monitoring of blood glucose levels
83026	Hemoglobin by copper sulfate – non-automated	Various	Monitors hemoglobin level in blood
84830	Ovulation tests by visual color comparison for human luteinizing hormone	Various	Detection of ovulation (optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
85651	Erythrocyte sedimentation rate – non-automated	Various	Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia

Final note: Carriers and A/B MACs do not need to search their files to either retract payment or retroactively pay affected claims processed prior to the implementation of this change, however, they will adjust claims that you bring to their attention

Additional Information

You can find the official instruction, CR5484, issued to your carrier or A/B MAC by visiting http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1195CP.pdf on the CMS website. As an attachment to that CR, you will find the complete list of laboratory tests granted waived status under CLIA.

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.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.