Internal Medicine Coding Alert

CDC and HCFA Announce New CLIA Waived Tests

The Centers for Disease Control and Prevention (CDC) in Atlanta, GA, has approved six more tests for inclusion on the list of waived tests under the Clinical Laboratory Improvement Amendments (CLIA), according to a program memorandum to carriers sent out by the Health Care Financing Administration (HCFA) on April 14.

Physician offices that have a laboratory with a CLIA certificate of waiver are allowed to perform these tests and seek reimbursement from federally-funded health care programs. The new tests are:

Bayer Clinitek 50 Urine Chemistry Analyzer for HCG, urine - to be reported with the new CPT code 84703QW.

Bayer Clinitek 50 Urine Chemistry Analyzer for microalbumin, creatinine - to be reported with the existing code 82044QW.

Bayer DCA 2000+ glycosylated hemoglobin (Hgb A1c) - to be reported with the code 83036QW

GDS Diagnostics HemoSite Meter for hemoglobin- to be reported with the code 85018QW.

ActiMed Laboratories E.N.A.C.T. Total Cholesterol Test (PDU) - to be reported with the code 82465QW.

Genzyme Contrast Strep A (direct from throat swab) - to be reported using the code 86588QW.

In order to bill to Medicare as a waived test, the CPT codes must be reported with the QW modifier (as shown above), the memorandum states.

CLIA Background

The Clinical Laboratory Improvement Amendments were passed by Congress in 1988 to establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed, according to a CLIA program description published on the HCFA website (www.hcfa.gov). The final CLIA rules were implemented in 1992.

Any facility that performs tests on specimens derived from humans for the purpose of diagnosing or preventing disease must meet standards set by the U.S. Department of Health and Human Resources (DHHS).

There are five levels of certification under CLIA:

Certificate of Waiver - issued to a laboratory to perform only waived tests.

Certificate for Provider-Performed Microscopy (PPM) Procedures - issued to a laboratory in which a physician, mid-level practitioner or dentist performs no tests other than PPM procedures. This certificate also permits the lab to perform waived tests.

Certificate of Registration - issued to a laboratory that enables the entity to conduct moderate- or high- complexity laboratory testing or both until the entity is determined by survey to be in compliance with the CLIA regulations.

Certificate of Compliance - issued to a laboratory after an inspection that finds the lab to be in compliance with all applicable CLIA requirements.

Certificate of Accreditation - issued to a laboratory on the basis of the labs accreditation by an organization approved by HCFA.

The majority of physician office laboratories (POLs) have either certificates of waiver or certificates for PPM procedures, according to HCFA data; 39.4 percent have certificates of waiver and 30.1 percent have certificates for PPM procedures. These labs are not subject to regular inspection by DHHS but are required to register with DHHS, obtain a certificate and CLIA number, and pay a certificate fee.

Note: To find out how to register your POL with DHHS contact your regional HCFA office. A list of addresses and phone numbers is available on HCFAs website at: http://www.hcfa.gov/medicaid/clia/regionof.htm.