## MEDICARE PART A BULLETIN

February 5, 1997

General Medicare Bulletin G-267

TO: All Medicare Providers

FROM: Andy DePirro, Director Program Relations

SUBJECT: COVERAGE ISSUES HCFA-PUBLICATION 6: LABORATORY TEST FOR CHRONIC RENAL DISEASE (CRD)

**ATTENTION MEDICARE BUSINESS OFFICE MANAGER:** Please distribute to all appropriate health care facility personnel.

The Health Care Financing Administration (HCFA) published this coverage clarification and new instructions, via the Medicare Coverage Issues Manual (HCFA-Publication 6), Transmittal 91. Even though these instructions were issued to providers via the HCFA manual revision process, the purpose of this bulletin is to ensure providers are aware of these Medicare coverage issue regulations.

# <u>Section 50-17, Laboratory Tests - CRD Patients: New Implementing Instruction -Effective for Services Rendered On and After February 27, 1997</u>

This section is revised to eliminate certain tests from the list of separately billable laboratory tests that are covered routinely without documentation of medical necessity. The Office of Health Technology Assessment (OHTA) issued two separate reports: one dated May 1994, Agency for Health Care Policy and Research (AHCPR) Pub. No. 94-0053; and one dated March 1996 AHCPR Pub. No. 96-0040.

The first report concluded that there was no reliable evidence to support the usefulness of performing nerve conduction tests (NCT), electrocardiograms (EKG), and chest X-rays routinely in patients with end stage renal disease (ESRD). The second report concluded that bone mineral density measurements currently do not provide useful information that could support therapeutic decisions in the management of ESRD patients. HCFA is eliminating routine coverage of these tests for ESRD patients. Medicare will continue to pay for NCTs, EKGs, chest X-rays, and bone surveys when there is documentation of medical necessity.

Medicare covers hepatitis-associated antigen tests once a month without additional documentation. The test that should be performed on a particular individual with ESRD depends on the serologic status of the individual and whether the person has been successfully immunized against hepatitis B virus. HCFA is clarifying the policy of routinely paying for hepatitis-associated antigen tests by

adopting the Center for Disease Control's recommendation that was outlined in OHTA's report dated

May 1994.

Questions regarding this bulletin may be addressed to the Medicare Part A Customer Service Department by calling (904) 355-8899.

#### SECTION 50-17 LABORATORY TESTS - CRD PATIENTS

**A.** Laboratory tests are essential to monitor the progress of CRD patients. The following list and frequencies of tests constitute the level and types of routine laboratory tests that are covered. Bills for other types of tests are considered non-routine. Routine tests at greater frequencies must include medical justification. Non-routine tests generally are justified by the diagnosis. The routinely covered regimen includes the following tests:

#### **Per Dialysis**

• All hematocrit or hemoglobin and clotting time tests furnished incident to dialysis treatments.

#### Per Week

- Prothrombin time for patients on anticoagulant therapy.
- Serum Creatinine
- BUN

#### Monthly

- CBC
- Serum Calcium
- Serum Potassium
- Serum Chloride
- Serum Bicarbonate
- Serum Phosphorous
- Total Protein
- Serum Albumin
- Alkaline Phosphatase AST, SGOT
- LDH

Guidelines for tests other than those routinely performed include:

Serum Aluminum - one every 3 months Serum Ferritin - one every 3 months

The following tests for hepatitis B are covered when patients first enter a dialysis facility: hepatitis B surface antigen (HBsAg) and Anti-HBs. Coverage of future testing in these patients depends on their serologic status and on whether they have been successfully immunized against hepatitis B virus. The following table summarizes the frequency of serologic surveillance for hepatitis B. Tests furnished

according to this table do not require additional documentation and are paid separately because payment for maintenance dialysis treatments does not take them into account.

### **Frequency of Screening**

Vaccination and Serologic Status	HBsAg Patients	Anti-HBs Patients
UNVACCINATED Susceptible	Monthly	Semiannually
HbsAg Carrier	Annually	None
Anti-HBs-Positive (1)	None	Annually
<u>VACCINATED</u> Anti-HBs-Positive (1)	None	Annually
Low Level or No Anti-HBs	Monthly	Semiannually

(1) At least 10 sample ration units by radioimmunoassay or positive by enzyme immunoassay.

Patients who are in the process of receiving hepatitis B vaccines, but have not received the complete series, should continue to be routinely screened as susceptible. Between one and six months after the third dose, all vaccinees should be tested for anti-HBs to confirm their response to the vaccine. Patients who have a level of anti-HBs of at least 10 sample ratio units (SRUs) by radioimmunoassay (RIA) or who are positive by enzyme immunoassay (EIA) are considered adequate responders to vaccine and need only be tested for anti-HBs annually to verify their immune status. If anti-HBs drops below 10 SRUs by RIA or is negative by EIA, a booster dose of hepatitis B vaccine should be given.

**B.** Laboratory tests are subject to the normal coverage requirements. If the laboratory services are performed by a free-standing facility, it must meet the conditions of coverage for independent laboratories.