Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal AB-03-132 **Date: AUGUST 22, 2003**

CHANGE REQUEST 2841

SUBJECT: Provider Education Article: Guidelines for Medicare Part B Laboratory Testing

Include this article in your next regularly scheduled bulletin and post it within two weeks of the issuance date of this Program Memorandum (PM) on any Web sites or bulletin boards you maintain. If you have a list-serv that targets the affected provider community, you must use it to notify subscribers that important information about diagnostic and screening prostate specific antigen testing and date of service for laboratory testing is available on your Web site. You are encouraged to provide in your bulletin any additional information you have developed to supplement or complement the article.

The effective date for this PM is September 5, 2003.

The implementation date for this PM is September 5, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after August 1, 2004.

If you have questions, please contact the appropriate regional office.

Attachment

Attachment

From the Medicare Learning Network @ CMS

Guidelines for Medicare Part B Laboratory Testing

This article explains the Centers for Medicare & Medicaid Services' (CMS) coverage policies for diagnostic and screening prostate specific antigen (PSA) laboratory tests under Medicare Part B. It also explains the importance of including the date of service on orders for laboratory testing.

Diagnostic PSA Laboratory Testing

- Under §4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33 mandated the use of negotiated rulemaking with interested parties in the laboratory community in order to promote uniformity, administrative simplicity, and program integrity regarding coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. As a result of this negotiated rulemaking, a National Coverage Decision (NCD) was developed for the diagnostic PSA test, which is a tumor marker for adenocarcinoma of the prostate and may be useful in the differential diagnosis of men presenting with as yet undiagnosed disseminated metastatic disease. When used in conjunction with other prostate cancer tests, such as digital rectal examination, the PSA test may assist in the decision-making process for diagnosing prostate cancer. PSA also serves as a marker in following the progress of most prostate tumors once a diagnosis has been established, as an aid in the management of prostate cancer patients, and in detecting metastatic or persistent disease in patients following treatment. The test is of proven value in differentiating benign from malignant disease men with lower urinary tract signs and symptoms (i.e., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia, and incontinence) as well as patients with palpably abnormal prostate glands on physical exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder.

- The NCD for diagnostic PSA tests does not apply to screening PSA tests.

- Use CPT/HCPCS code 84153 for diagnostic PSA testing.

Screening PSA Laboratory Testing

- Screening PSA testing measures the level of prostate specific antigen in the patient's blood for the early detection of the marker for adenocarcinoma of the prostate subject to coverage, frequency, and payment limitations as follows:

  - Covered at a frequency of once every 12 months for men who have attained age 50 if at least 11 months have passed following the month in which the last Medicare-covered screening PSA test was performed; and

  - Must be ordered by the patient's physician, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife who is authorized under State law to perform the examination, fully knowledgeable about patient's medical condition, and who would be responsible for using the results of any examination (test) performed in the overall management of the patient's specific medical problem which includes explaining the results of the test to the patient.

- Use HCPCS code G0103 for the screening PSA test.

Date of Service for Laboratory Testing

During the clinical diagnostic laboratory services negotiated rulemaking, CMS learned that there was considerable variability regarding the date of service on laboratory claims. In order to promote uniformity, the committee recommended a national policy related to the date of service on laboratory claims. CMS published a proposed rule for public comment on March 10, 2000 (65 FR 13082) and published the rule final on November 23, 2001 (66 FR 58788). The final rule states that:

- The date of service for laboratory tests that is reported on the claim is to be the date the tested specimen was collected; and

- The person obtaining the specimen must furnish the date of collection of the specimen to the entity billing Medicare.

Physicians or their staff who draw specimens for testing **must** report the date of collection of the specimen on orders for laboratory tests. Laboratories may refuse to perform tests on orders for laboratory tests that do not include the information they need in order to seek payment for services performed, i.e., the date of collection of the specimen.