

Home Bladder Cancer Test: A Case Study

Medicare patients suffering from bladder cancer cannot gain access to this prescription home-use test because HCFA's payment policies have led to confusion among its local contractors and, in most cases, have resulted in non-payment for the test.

Summary

Confusion and uncertainty over the Health Care Financing Administration's (HCFA) decision to cut payment by roughly 70 percent for this test has led Medicare's local contractors to stop payment for the test altogether, thus virtually stopping all access for Medicare patients. The change in reimbursement results from HCFA's judgement that it will no longer permit providers to use the "immunoassay for tumor antigen" code when they bill for the device—even though FDA approved the device as an immunoassay for tumor antigens (proteins created by cancer cells). HCFA insists that providers must now use a much lower-paying code—thus cutting payment some 70 percent—even though the American Medical Association believes the original code is appropriate and HCFA's contractors in 40 states accepted the original code for more than a year.

This change in HCFA policy has created confusion and uncertainty among Medicare's local contractors about the most appropriate code for the device. As a result, virtually all of them have halted payment for the test when used in the home or in a physician's office. The grossly inaccurate coding also threatens the viability of the product in the marketplace. HCFA's actions risk permanently limiting Medicare patient access to a product that was named the most innovative product of 1999 by *Medical Device and Diagnostic Industry* magazine.

Product

The test is used to detect bladder cancer in patients who are undergoing monitoring for cancer recurrence. It evaluates a few drops of a patient's urine to determine whether a protein produced by cancer cells is present. The device uses highly specific monoclonal antibodies to bind to the tumor antigen. A positive result is indicated by a line that appears within five minutes in a display window on the front of the device.

Although the device may be prescribed by a physician for use at home, it is not to be used as a mass screening test. The FDA has cleared the test only to monitor those patients previously diagnosed with bladder cancer. The test is a medically useful and cost-effective alternative to currently practiced diagnostic procedures.

Case History

In December 1998, FDA cleared the test for prescription home use. The labeling that the FDA approved characterized the product as an immunoassay test for detecting a bladder tumor antigen produced by bladder cancer cells. This antigen is an indicator—or "marker"—of bladder cancer. Therefore, doctors billed for the product using CPT procedure code 86316, which is entitled "Immunoassay for tumor antigen" and which paid \$27.50 for the test. The American Medical Association, which maintains the CPT coding system, reviewed the coding designation in March, 1997, and again in June, 1999, and agreed that procedure code 86316 was the appropriate code.

Medicare carriers in at least 40 states had been reimbursing laboratories using the 86316 code since April 1997, when the test first became available. At that time, it had FDA clearance for use only in clinical laboratories, not in the home. Once FDA cleared the test in December 1998 for prescription use in the home (and the Centers for Disease Control agreed that it could be "waived" under the Clinical Laboratory Improvement Amendments¹), physician offices that prescribed the test should have been able to receive reimbursement for it beginning in February, 1999.

However, HCFA issued a national program memorandum, dated June 1999, indicating that it would not accept CPT code 86316 when the device was used in the home. HCFA directed its contractors to accept only CPT code 83518QW ("Urinalysis dipstick") which pays about \$8.00—a net payment reduction of roughly 70 percent. This lower-paying code is equivalent to the code assigned to urine chemistry tests. Urine chemistry tests are used for mass screening and are based on simple chemical reactions. By contrast, the bladder cancer test utilizes monoclonal antibodies directed against a tumor antigen and is used by a much smaller patient population.

Though the HCFA program memorandum was dated June, 1999, actual distribution of the memorandum did not begin until August, 1999. As of mid-September, 1999, more than 50 percent of local Medicare contractors still did not acknowledge that this program memorandum was ever sent to them. Thus, confusion both over HCFA's decision to change the code—in conjunction with its delays in disseminating the memorandum explaining the change—have created uncertainty among Medicare's local contractors about the most appropriate code for the device. As a result, virtually all Medicare contractors have halted payment for the test, for claims related to prescription home use and physician offices. This accounts for at least 90% of the test usage.

It is interesting to note that the company was not informed of the coding change by HCFA or its contractors; nor was it given a chance to present its view or provide input about the change prior to it occurring. HCFA took this approach even though the coding change has the potential for seriously harming the product.

¹ Waiver by the Centers for Disease Control effectively means that the test can be used in a patient's home or in a physician's office.

Impact of HCFA Coding Decision

As indicated earlier, virtually all of HCFA's local contractors are denying claims from physicians' offices for the device. In order for patients to continue to have access to the test, the company has chosen to simply take a financial loss in continuing to supply it to physicians. This is difficult because the company is small and the device could constitute an important revenue stream. Reduced availability affects patients directly because, in some cases, the test can be an alternative for a much more invasive procedure which is often traumatic for patients. The device is also considerably less expensive and more sensitive than conventional diagnostic procedures. Therefore, the test is better at detecting recurring cancer sooner, thus allowing for lower overall healthcare cost and improved patient survival.

Recommendations

HIMA supports legislation designed to reduce the length of time from FDA clearance of a technology to the time when it is appropriately reimbursed by HCFA and available to patients who need it. The following HIMA recommendation is designed to help achieve that goal and to address specifically some of the challenges described in this case study:

- HCFA should utilize an advisory committee that examines Medicare coding and payment. This panel would examine how payment, coding, and coverage systems interact and would recommend steps to correct any problems that impede the smooth integration of medical technology into Medicare. This includes monitoring of HCFA's performance in administering various coding issues.