

Coronary Stents: A Case Study

For several years, this breakthrough medical technology was provided to less than 25 percent of eligible Medicare patients. However, once HCFA's reimbursement rates improved, coronary stents—the standard of care—were provided to 70-80 percent of eligible Medicare patients.

Summary

For several years after the FDA approved the coronary stent in 1994, the Health Care Financing Administration (HCFA) paid \$3,000-\$5,000 below what it cost hospitals to provide this breakthrough device for critically ill patients with heart disease. This low payment level meant that hospitals had to make up the difference in cost themselves if they wanted to provide the stent to their Medicare patients. Thus, HCFA's payment policies gave hospitals strong incentives to minimize use of the product among patients who could benefit from this new technology. HCFA's underpayment arose directly from its highly complex rules for establishing payment rates—particularly its demands regarding the nature of the data it would accept in determining such rates.

In addition, a number of significant delays were encountered in obtaining appropriate Medicare coding and payment for coronary stents. The first challenge was to obtain a unique code for the stent from HCFA—a process that took several years. The reason for the delay in setting an appropriate payment: HCFA required a complete year of data on the costs of the device, rather than accepting a statistically valid sample. The net effect was that—after FDA approved the product in August 1994—hospitals did not receive adequate payment for the device for three years until HCFA finally okayed appropriate payment levels in October 1997.

HCFA's three-year underpayment for the coronary stent had a clear impact on patients. Prior to the time that appropriate payment rates went into effect in 1997, only 5 to 25 percent of Medicare patients who were eligible for the coronary stent received it. After HCFA okayed reasonable payment in 1997, use of the stent rose to more than 50 percent of patients. Today, about 70 to 80 percent of patients who are eligible for the therapy receive this breakthrough technology.

Product

A stent is a small, slotted, stainless steel tube that is inserted into coronary arteries to reduce narrowing and permit blood to flow normally through the artery. The stent is delivered to the site of the blocked artery by a balloon catheter. The device was approved by the Food and Drug Administration in August 1994.

This breakthrough device has markedly increased the safety of angioplasty performed in cardiac patients and has led to substantial reductions in emergency bypass surgeries. In fact, it has practically eliminated them. The coronary stent has also made it possible for patients to receive angioplasty who might not have been able to undergo it previously and reduced the need for repeat angioplasty and by-pass surgery. Today, coronary stenting appears to be a viable alternative to by-pass surgery for many patients with extensive coronary artery disease.

Case History

HCFA was asked in 1990 to establish a unique procedure code for the coronary stent. Procedure codes are used to identify specific medical treatments and therapies. Obtaining a unique code for the stent was critical because such a code would permit HCFA to track the costs and charges for the device—an essential first step in determining a payment level that reflected the true costs of the stent. Unfortunately, HCFA's methods for creating codes are often very slow. HCFA did not finally approve a new code for the stent until 1995—five years after the code was first requested.

However, obtaining a code is only the first step in securing reimbursement under Medicare. HCFA then had to assign the product to a payment category—called a Diagnosis Related Group (DRG). The DRG determines the exact payment that hospitals will receive for providing the treatment to Medicare patients. Consistent with its long-standing practice, HCFA automatically assigned the stent to the existing DRG that it believed most closely approximated the nature of the stent treatment—without regard to the actual cost of the product to the hospital. The reimbursement level for that DRG, however, was—as noted previously—\$3,000-\$5,000 below what it actually cost hospitals to provide the device to patients. This low payment level meant hospitals had to make up the difference in costs themselves if they wanted to provide the device, and its accompanying clinical benefits, to Medicare patients. It also meant that hospitals had clear incentives to minimize using the stent or to substitute a less costly and less effective therapy.

Despite this, HCFA said that before it could assign the device to a higher-paying DRG—as had been requested—it needed one complete year of data on the actual charges for hospital cases using the device. However, the entire process would actually take two years—one year to collect the data, and one year to analyze them.

In an attempt to shorten the process, an independent consulting firm analyzed a valid, statistically-representative sample of cases in which the stent was used. The consultant extrapolated this sample to show a full year of data on charges for the device. The findings indicated that the actual charges for the stent were well in excess of the level of reimbursement provided to hospitals by the Medicare DRG that HCFA had assigned to this technology. Despite this information, HCFA said that—based on long-standing precedent—it would not use the findings to reassign the stent to a higher-paying DRG because they were based on sample data. HCFA insisted on a complete set of data covering a full fiscal year.

Not until 1997, when full-year data were finally available and fully analyzed, did HCFA agree that the product belonged in a higher-paying DRG, and, in October 1997, HCFA reassigned the stent accordingly. This was two years after the procedure code had been assigned for the product, three years after FDA approved the product, and some seven years after the code had first been requested.

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 recommendations help achieve that goal and address specifically some of the challenges described in this case study:

- HCFA should be directed to use valid, verifiable external sources of information to update payment categories if Medicare's data are limited or not yet available. This includes accepting a valid, statistically representative sample from such sources as private insurers, independent clinical research organizations, manufacturers, suppliers, and other appropriate non-Medicare entities.
- HCFA should be directed to 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 rapid, smooth integration of medical technology into Medicare. This includes monitoring HCFA's performance in administering various coding issues. One of the objectives of this panel would be to recommend mechanisms for reducing the length of current coding processes and to monitor HCFA progress in instituting improvements in them.