While Congress was publicly debating a prescription-drug benefit for older patients last year, the Medicare program quietly announced plans to provide coverage for three invasive, high-cost procedures that potentially could affect its 41 million enrollees. The Centers for Medicare and Medicaid Services (CMS), which administers Medicare, opted to pay for lung-volume-reduction surgery, implantable cardioverter-defibrillators, and left ventricular assist devices — three weighty decisions issued during a four-month period.

**LUNG-VOLUME-REDUCTION SURGERY**

The saga involving lung-volume-reduction surgery began in 1995, when the CMS discovered that it was inadvertently paying for the procedure. Surgeons were simply calling the operation “bullectomy,” a different procedure with a legitimate billing code, since lung-volume-reduction surgery did not have a code. The new procedure involves either mediastinoscopy or video-assisted thoracoscopic surgery. The damaged part of the lung is cut away and the remainder stapled together. In 1995, Medicare issued a decision that it would not cover the procedure, on the grounds that there was no evidence on which to decide whether the operation was effective. It then took the unusual step of helping to launch a clinical trial that was designed to provide a decisive answer to the question of efficacy.

The overall results of the five-year, multicenter, randomized trial — a cooperative effort involving the CMS, the National Heart, Lung, and Blood Institute, and the Agency for Healthcare Research and Quality — were published in May 2003. This invasive surgical procedure, performed in older patients whose daily functioning was substantially limited by their advanced chronic obstructive pulmonary disease, conferred a small improvement in exercise tolerance. After excluding a group of patients who were determined to be at very high risk of death, the researchers found that exercise capacity was increased in 16 percent of the surgically treated patients, as compared with 3 percent of the patients who were treated medically. There was no significant difference in mortality between the two groups.

The CMS moved quickly to begin the process of determining whether it would pay for the procedure. In August 2003, after studying the data in detail, the agency announced that it would offer the surgery to selected subgroups of patients identified in the trial. It agreed to make lung-volume-reduc-
tion surgery available to patients who were not at high risk of death from the procedure and whose disease affected the upper lobes of the lungs exclusively. The agency also offered the surgery to non-high-risk patients who had a combination of diffuse disease and low exercise capacity. Publication of a formal National Coverage Determination, including instructions to insurance carriers (a process that may take several months), signals that Medicare will cover the procedure. The surgery then will be available in approved medical centers to the approximately 10,000 to 20,000 Medicare beneficiaries who are candidates for it each year, at an estimated cost of $600 million to $1.2 billion.8,9

**IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS**

The path to approval of coverage for the implantable cardioverter-defibrillator was a little different, though the outcome — coverage for Medicare beneficiaries meeting specified criteria — was similar. Defibrillators, which like conventional pacemakers are battery-operated devices implanted under the skin with wires threaded into the heart, are intended to prevent sudden death. In 2001, building on earlier studies showing that defibrillators were helpful in patients with inducible ventricular arrhythmias, the Multicenter Automatic Defibrillator Implantation Trial II studied a group of patients with a previous myocardial infarction who had an ejection fraction of less than 30 percent and no overt evidence of arrhythmia. The trial showed an absolute decrease of 6 percent in the risk of death among treated patients, as compared with those who were treated medically, with a relative risk reduction of 31 percent. Patients with defibrillators had a higher risk of hospitalization for heart failure than did medically treated patients.7

In 2002, Guidant, the leading manufacturer of defibrillators, submitted a request to the CMS to expand Medicare coverage to include the population identified by the new study. In this instance, the CMS convened a committee to examine all the data and make a recommendation. Chaired in 1998 by the Department of Health and Human Services, the Medicare Coverage Advisory Committee was established to "advise CMS on whether specific items and services are reasonable and necessary under Medicare law." The committee members "perform this task via a careful review and discussion of specific clinical and scientific issues in an open and public forum."8 The committee is made up of 100 representatives from science, medicine, economics, and biomedical ethics; a subgroup of the committee is invited to meet with nonvoting representatives of both the public and industry to make recommendations to the CMS in cases of "significant controversy." The Medicare Coverage Advisory Committee met in February 2003 and unanimously supported coverage of defibrillators for the primary prevention of sudden death in patients meeting the criteria of the latest clinical trial.

During the next four months, the CMS sought the recommendation of an external consultant and commissioned a thorough review of the data by its internal Coverage and Analysis Group. This group obtained additional information not available to the Medicare Coverage Advisory Committee, which showed that much of the benefit seen in the study could be accounted for by patients with inducible ventricular tachycardia and that only the subgroup of patients with a conduction abnormality (a QRS duration greater than 120 msec) had a statistically significant decrease in mortality with defibrillator therapy. As a result of these analyses, Medicare announced its intention to expand coverage of defibrillators, but only to a subgroup of patients eligible for inclusion in the recent study. The CMS also promised to revisit this decision when an additional study, then in progress, was completed.9 Implantable defibrillators cost $35,000 per person and could be beneficial in 10,000 to 90,000 patients each year, for a total annual cost of $350 million to just over $3 billion.10

**LEFT VENTRICULAR ASSIST DEVICES**

The process of deciding about coverage for left ventricular assist devices included elements of the decisions regarding both defibrillator implantation and lung-volume-reduction surgery, but the outcome was slightly different. The CMS announced it would cover the implantation of the devices in selected circumstances and at particular institutions, but, in a separate decision, the agency set the reimbursement rate at a level below the market cost.11

Left ventricular assist devices were initially used as a stopgap measure in patients with New York Heart Association class IV heart failure who were awaiting heart transplantation. These devices consist of a prosthetic pumping chamber, which is inserted in the peritoneal cavity, with an inflow cannula connected to the left ventricular apex and an
our flow valve anastomosed to the ascending aorta. The patient wears an external unit comprising electronic controls and a battery pack.

A team of investigators based at 20 transplantation centers conducted a randomized study to determine whether the left ventricular assist device could be used as a definitive treatment, rather than a temporary one, for patients who, because of age or co-existing illness, were not candidates for a heart transplant. The study showed a 48 percent decrease in the rate of death from all causes among the 68 patients randomly assigned to receive the device, as compared with the 61 patients who received optimal medical care. However, even with the pump, the survival rate was only 52 percent at one year and only 23 percent at two years. Among the recipients of the left ventricular assist device, the quality of life (as measured by a variety of standard instruments) had improved at one year, though in the first three months, 28 percent of the patients had infections, some of which were fatal, and 42 percent had bleeding.12

Sixteen months after the study of left ventricular assist devices was published, the Medicare Coverage Advisory Committee met to consider paying for the device. In March 2003, the committee voted six to one that the device offered "substantial benefit to patients with severe congestive heart failure."23 The group recommended restricting the use of the device to patients who met the study criteria and advised that only heart-transplantation centers be authorized to perform the surgery.

On the basis of the advisory committee’s recommendations, a decision by the CMS about whether and under which circumstances it would cover the device was expected in June 2003. It was repeatedly postponed because of concern about the procedure’s cost, but finally, in October 2003, the CMS agreed to provide coverage if the operation is performed in selected heart-transplantation facilities that use a stringent process for obtaining informed consent. In a separate but related decision, the CMS agreed to modify the diagnosis-related group code for the procedure and to increase the reimbursement by 25 percent, to about $70,000.24 Hospitals may qualify for additional payments depending on their geographic location and other factors, but there will still be a substantial shortfall, since the CMS acknowledges that the average charges for the procedure exceed $200,000,22 with the device alone costing $65,000. Since 5000 Medicare patients are expected to qualify for the device initially — and that number could rise to 100,000 — the cost to Medicare is expected to be $350 million to $7 billion per year.25

THE DECISION-MAKING PROCESS

This brief summary of the process used by the CMS to arrive at coverage decisions for lung-volume-reduction surgery, implantable defibrillators, and left ventricular assist devices demonstrates that in many ways it is a model of thoughtful deliberation.20 As reiterated by Tom Scully, who was administrator of the agency at the time that these decisions were made, each of the recent decisions was based on "an exhaustive evaluation of the available scientific evidence."17,26 Further revisions, introduced in September 2003, were designed to make the process even more "open and understandable."20 The Coverage and Analysis Group of the CMS, drawing on either a technology assessment performed by the Agency for Healthcare Research and Quality or a comprehensive review by the Medicare Coverage Advisory Committee for particularly thorny cases, "evaluates whether reported benefits translate into improved net health outcomes."12 The CMS then issues a decision memorandum, a document that informs the public of its decision and the reasons for it, describes the process that was followed, and summarizes the evidence that was considered.17

Decisions regarding Medicare coverage are founded on a legal requirement stipulating that the agency must reimburse patients for "items and services which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."21 The CMS has been forced to weigh several factors in making reimbursement decisions. The decisions it reaches could be quite different if CMS were to follow explicit guidelines for integrating costs and values into its decision making.

COST-EFFECTIVENESS ANALYSIS

The framework that is best established for considering costs and values is cost-effectiveness analysis. When carried out from a society-wide perspective in accordance with accepted standards, cost-effectiveness analysis considers the marginal cost of a new procedure for each quality-adjusted year of life that a patient gains.22

To be covered, a new procedure must be supported by scientific evidence that it offers patients a
clinically meaningful benefit. If, in addition, a procedure were required to demonstrate a cost-effectiveness ratio of not more than $50,000 to $100,000 per quality-adjusted life-year ($50,000 is a widely used benchmark reflecting the cost of dialysis in a patient with end-stage renal failure), the CMS would not have approved coverage of either lung-volume-reduction surgery or implantation of the left ventricular assist device. However, on the basis of those criteria, it might have approved implantation of the defibrillator.

As computed by Blue Cross and Blue Shield, the cost-effectiveness ratio for the left ventricular assist device, when applied to the population for which it was approved by the CMS, ranges from $500,000 to $1.4 million per quality-adjusted life-year, depending on the assumptions about the cost of the procedure and the life expectancy of the recipients. A companion piece to the report by the National Emphysema Treatment Trial on lung-volume-reduction surgery, written by the study's authors, stated that in the three subgroups of patients for whom the CMS approved coverage, the procedure had cost-effectiveness ratios of $98,000 per quality-adjusted life-year (for patients with upper-lobe disease and low baseline exercise capacity), $240,000 per quality-adjusted life-year (for patients with upper-lobe disease and high exercise capacity), and $330,000 per quality-adjusted life-year (for patients with diffuse disease and low exercise capacity).

On the other hand, using the criteria outlined above, the CMS might have approved coverage of the cardioverter-defibrillator. Although the published analyses of the defibrillator are based on studies other than the multicenter trial, they show that the cost-effectiveness of the device improves with risk stratification. This suggests that extrapolation of the data to patients who meet the clinical criteria approved by the CMS would result in ratios of $30,000 to $85,000 per quality-adjusted life-year.

**OTHER FACTORS**

Additional value judgments, outside those customarily included in analysis of cost effectiveness, may influence the weighing of the risks and benefits of medical treatment. For example, ethicists, policymakers, and the general public often favor according preference to those who are worst off. This view translates into giving special consideration to palliative care services for the dying, as was done by Oregon in the comprehensive rating system it developed to set priorities for care within Medicaid. However, such judgments might best be made explicit.

**THE NEED FOR EXPLICIT CRITERIA**

The CMS has tried several times to make rules that would guide its decisions about national coverage. Conceivably, such rules could include guidelines for acceptable levels of cost effectiveness and recommendations for special treatment of particular kinds of care, such as interventions aimed at end-of-life care. In 1980, the CMS's predecessor, the Health Care Financing Administration (HCFA), drafted a policy that proposed adopting criteria based on economic, safety, ethical, and other considerations. According to Washington insiders, the rule was quashed at least in part by the medical-device industry. Nearly 10 years later, HCFA announced that it was planning to issue a rule incorporating considerations of appropriateness and cost effectiveness into decision making. This rule was also defeated. In its latest revision of the process for making coverage decisions, the CMS stated that "given that there are substantial competing interests about the coverage criteria, we believe it best not to pursue rulemaking. In the meantime, as we have done in the past 35 years, we [will] continue to . . . . make coverage decisions and to interpret what is 'reasonable and necessary.'"

The inability of the administrative legal system to institute more explicit criteria for coverage suggests that congressional action may be needed to refine the existing standards. A debate in Congress over legislation to revise the "reasonable and necessary" criteria would give the problem of determining Medicare coverage of new procedures and devices the public attention it deserves.

When Medicare was established in 1965, broad coverage of technological innovations seemed reasonable. However, adopting new criteria for making such decisions is imperative now that Medicare, whose budget reached $277 billion in 2003, is confronted with procedures of unprecedented cost and highly variable clinical benefit. Just as Congress recently added a prescription-drug benefit — an acknowledgment that both the role and the cost of medications have changed profoundly since 1965 — so too must it grapple with defining criteria for coverage of technological innovations.
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