

# Delay Sought in Medicare Heart Procedure Cuts

*Proposed slashes in payments for stents and other devices would discourage their use, groups assert.*

BY ALICIA AULT  
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WASHINGTON — Patient access to technologies such as drug-eluting stents and implantable cardioverter defibrillators may be severely reduced if a Medicare proposal becomes final, physicians and others said at a press conference sponsored by a coalition of device makers, patient advocates, and medical and surgical societies.

The organizations are calling for a 1-year delay in implementation of the Centers for Medicare and Medicaid Services' April proposal to overhaul diagnosis-related group calculations and reduce reimbursement to hospitals for a variety of mostly cardiac procedures. If not delayed, the Hospital Inpatient Prospective Payment System rule would become final in late July or early August and go into effect in October.

"If adopted, this proposal would implement the most dramatic change in hospital payment rules in nearly 20 years," said Stephen J. Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed), a medical device lobbying group.

CMS is seeking to move from a charge-based system to a cost-based system. AdvaMed is not opposed to the switch, but CMS's methodology—which will rely on outdated information—is flawed, Mr. Ubl said. For instance, 2007 payments would be based on 2003 cost reports.

Dr. Mark A. Turco, an interventional cardiologist at Washington Adventist Hospital in Takoma Park, Md., who spoke on behalf of the Society for Cardiovascular Angiography and Interventions, noted that drug-eluting stents were not available for most of 2003.

CMS has proposed slashing stent payments by 23%-33%. As a result, the society "is worried that hospitals will inappropriately discourage the use of the newest and most costly technologies," Dr. Turco said.

He also mentioned that as it stands, CMS pays for implantation of only one drug-eluting stent per vessel and that some hospitals are already limiting how many stents can be used, but that surgeons are pushing those limits—the mean is 1.4-1.7 stents per procedure right now, he said. The concern is that if CMS

clamps down further, it might be very hard to use more than one stent in a vessel, even if it's needed.

Thoracic surgeons are concerned the cuts will lead hospitals to put the squeeze on specialty teams that provide invaluable assistance and care, especially in emergent or urgent procedures like transplantation or replacement of infected valves, said Dr. Frederick L. Grover, president of the Society of Thoracic Surgeons.

In a statement, Dr. Dwight W. Reynolds, president of the Heart Rhythm Society, said the proposed cuts for implantable cardioverter defibrillators (22%-24%), pacemakers (12%-15%), and ablations (28%), would not only discourage these procedures, but might also hinder quality improvement efforts. Hospitals could reduce resources devoted to a largely voluntary collection of outcomes data, he said.

The American Hospital Association alerted its members in early June that it did not oppose a return to cost-based payments, but said CMS's methods are flawed. The AHA board recommended a 1-year delay in the rule.

Device maker Medtronic Inc. urged



The cuts would hinder care for all patients, not just those on Medicare, Dr. Mark A. Turco said.

physicians in a letter to write to CMS to oppose the cuts. The new scheme "could reduce patient access to interventional procedures," wrote Scott R. Ward, president of Medtronic Vascular. "We are confident that a substantive and comprehensive response to the CMS proposal will have an impact," he wrote.

Dr. Turco noted that the changes will affect care for all patients. "If implemented, these changes may very well make it difficult for physicians to deliver to Medicare beneficiaries, and all patients, the innovative medical care that has led to declines in mortality from cardiovascular disease." ■

## Insurers Likely Will Expand Coverage for Cardiac Rehab

BY DAMIAN McNAMARA  
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MIAMI — Private insurers are likely to follow the Centers for Medicare and Medicaid Services in a move to expand coverage for cardiac rehabilitation services, according to a presentation at the annual meeting of the American Medical Society for Sports Medicine.

"In March 2006, Medicare made a big shift for cardiac rehab," the first major coverage change in decades, Steven Keteyian, Ph.D., said. Since the 1980s, Medicare has covered cardiac rehabilitation for patients following a heart attack, coronary artery bypass surgery, or angina.

The expanded coverage includes heart valve repair or replacement, percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting, and heart or combined heart-lung transplantation. These CMS changes are important because private insurers usually follow suit.

"Missing for me is the heart failure patient," said Dr. Keteyian, program director of Preventive Cardiology at Henry Ford Hospital in Detroit. Data are insufficient regarding benefits of rehabilitation in patients with heart failure, although current studies might provide some answers.

Previously, CMS reimbursed only the exercise component of cardiac rehabilitation. Now coverage includes medical evaluation, risk factor modification, exercise, and education.

Historically, rehabilitation was limited

to 36 visits in 12 weeks. Now physicians have up to 18 weeks to complete the same number of visits, Dr. Keteyian said. "This will give us a lot of flexibility in how we manage these patients." In addition, following a review and approval, rehabilitation can be extended to 72 visits over 36 weeks.

ECG rhythm strips were mandatory for reimbursement prior to the policy change. Now the need for such monitoring is at the discretion of the physician.

Previously, requirements for physician supervision were unclear, Dr. Keteyian said. CMS only stipulated that physicians were proximal to the exercise area. More specific requirements now state that physicians should be on the premise or within 250 yards if the area is in a separate building on the hospital campus. They must be immediately available if the rehabilitation unit is freestanding, Dr. Keteyian said.

CMS had proposed identifying the "incident to" physician as the ordering physician only. However, the agency decided it would not be appropriate to have "incident to" rules specific for cardiac rehabilitation. The "incident to" physician can therefore be the ordering physician, a primary care physician, or a program medical director.

Not all patients will take advantage of the added coverage, Dr. Keteyian said. "We are doing an okay job with discharge recommendations—54% to 74% recommend cardiac rehab." However, actual utilization is in the "25% to 40% range," possibly because of insurance, social issues, or because of transportation concerns. ■

## CMS Will Pay for Charité Disk In Patients Younger Than 60

BY ALICIA AULT  
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In a final Medicare coverage decision, regional contractors have been given the leeway to pay for implantation of the Charité artificial lumbar spinal disk, but only in beneficiaries who are younger than 60 years of age—about 6 million people.

The Centers for Medicare and Medicaid Services had originally proposed that the disk not be covered in any circumstances. After examining the evidence, however, CMS decided that although the data were unconvincing and "[did] not provide a sufficient basis for a national coverage decision at this time," regional Medicare payers could reimburse for the procedure.

CMS also concluded that it would not be reasonable or necessary to cover the Charité disk for people over age 60. That position was supported by the North American Spine Society, the Scoliosis Research Society, and the Spine Arthroplasty Society. The American Association of Neurological Surgeons and the Congress of Neurological Surgeons had argued in comments on the proposal that the surgeon should decide which patients would benefit from the procedure.

CMS was lobbied to cover the procedure for all patients. The agency reported that it received a total of 604 comments, 470 of which were a form letter

that had been created by the Texas Back Institute and were signed by patients, family members, and others. The agency said it was "skeptical" of form letters, and that it was not clear how many of the signees were Medicare beneficiaries.

Only seven of the comments overall backed the agency's proposal to not cover the procedure nationally. One physician told CMS that DePuy Spine Inc. was "orchestrating an aggressive letter-writing campaign asking surgeons to write CMS and request that coverage be granted." Because of the pressure, he said that he felt compelled to come out against coverage.

"I believe that the DePuy strategy is self-serving and is clearly intended to bolster the device's stagnant sales figures," the physician alleged.

Charité, made by DePuy Spine of Raynham, Mass., was approved in late 2004 for 18- to 60-year-old patients with either level L4/L5 or L5/S1 degenerative disk disease. It has not been studied in patients over the age of 60.

DePuy reported that 5,000 disks have been implanted since its approval, but only 205 procedures have been covered by insurers.

"We hope this decision will provide further support to other insurers of the importance of the Charité as a treatment option for patients with degenerative disk disease," Dr. Richard Toselli, DePuy worldwide vice president for research and development, said in a statement. ■