

American Academy of Medical Administrators

Developing Excellence in Healthcare and Leadership

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AMERICAN COLLEGE OF CARDIOVASCULAR ADMINISTRATORS

March 5, 2003

The Honorable Thomas Scully
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
P.O. Box 8010
Baltimore, Maryland, 21244-8018

RE: Medicare Program – Inpatient Prospective Payment System – Fiscal Year 2004 Rates

Dear Administrator Scully:

The American College of Cardiovascular Administrators appreciates the opportunity to submit comments related to the soon-to-be released 2004 hospital inpatient prospective payment system, to be published in the *Federal Register*. Our comments are submitted on behalf of all cardiovascular programs and administrative professionals across the United States.

The American College of Cardiovascular Administrators (ACCA) is a specialty group of the American Academy of Medical Administrators (AAMA) and is comprised of over 3,000 members representing all sectors of the healthcare administrative field. Specifically, the ACCA/AAMA is a nonprofit professional society for individuals involved in the administration of cardiovascular and other specialty services at hospitals and clinics across the United States whose purpose is to develop and refine concepts and practices in the field of cardiovascular and other specialty healthcare administration and to promote the advancement of its members in knowledge, professional development, and personal achievements through continuing education, research, and advocacy in healthcare management. Our members are the primary personnel responsible for the implementation and management of issues – technology and otherwise – impacting cardiovascular programs across the country.

We appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS), specifically related to the acknowledgement of emerging technologies such as drug-eluting stents. We recognize that the pre-FDA approval inclusion of reimbursement for technologies such as drug-eluting stents represents a precedent-setting move on the part of CMS. We further appreciate the fact that CMS recently convened an advisory panel to review reimbursement criteria for automatic implantable cardioverter-defibrillators.

Summary

Drug-Eluting Stents: CMS seems to have assumed a one-to-one conversion from bare metal stents to drug-eluting stents in terms of utilization. This approach most likely seemed logical last year prior to having access to actual per case utilization data out of Europe which suggests that actual utilization per case is much higher than with bare metal stents. As such, the full cost of implementing the new

technology will not be covered under the proposed rate increase from DRGs 516/517 to DRGs 526/527. ACCA is concerned that utilization of drug-eluting stents will mirror the European experience and be much higher on a per case basis. The apparent one-to-one conversion applied in determining rates for DRGs 526/527 is therefore inadequate.

Automatic Implantable Cardioverter-Defibrillators: Relative to implantable cardioverter-defibrillators (ICD), CMS has yet to formally address MADIT II criteria for prophylactic implantation of an ICD in patients meeting specific (FDA-accepted) clinical criteria. Physicians and hospitals are both ethically and legally bound to implant an ICD in a patient meeting these criteria. Lawsuits already exist on this subject, and the overall volume of ICD implants will undoubtedly increase. Physicians and hospitals cannot afford to meet FDA-accepted criteria for implant of an ICD and not be paid appropriately for the service rendered. CMS did convene a Medicare Advisory Committee recently to discuss the issue of reimbursement for ICD implantation, and the Advisory Committee has recommended expanding Medicare coverage for these procedures and technology.

Drug-Eluting Stents

Much has been written and said about drug-eluting stent (DES) technology and its potential impact on the field of cardiovascular medicine. Although it is too early to gauge accurately the entire impact this technology will have on the field (FDA approval is pending), there is a growing body of evidence suggesting that DES technology will change the standard of care for coronary artery disease. Additionally, it seems quite clear that utilization per case will be much greater than what CMS anticipated in its calculations that lead to the creation of DRGs 526 and 527. These DRGs, which become effective April 1, 2003, provide additional reimbursement of \$1,655 to \$1,818 over reimbursement for traditional bare-metal stents.

2003 Coronary Stent DRGs and Corresponding National Average Payments

DRGs and Classification Structure		National Average Payment
516	Coronary (bare metal) stent procedure with AMI	\$12,704
517	Coronary (bare metal) stent procedure without AMI	\$10,150
526	Coronary drug-eluting stent procedure with AMI	\$14,522
527	Coronary drug-eluting stent procedure without AMI	\$11,805

AMI refers to Acute Myocardial Infarction; national average payments based on large urban areas.

While 2003 DRG rates for DES procedures represent an improvement over bare metal DRG rates, these inpatient payments will not be sufficient to cover concomitant DE stent procedure resource use. Further, because of litigation fears and the profound improvement in clinical outcomes associated with DES utilization as reported via clinical investigation, many hospitals expect to experience a change in treatment patterns essentially overnight. Because of this immediate shift (potentially 100 percent of cases), hospitals are appropriately concerned that inadequate payments will cause significant financial deficits for cardiovascular programs and health care institutions.

Institutional concerns are based on the belief that this technology will enable interventional cardiologists to begin treating intracoronary lesions that would have previously required surgery. Further, there are many who believe that cardiologists will no longer treat only the “culprit” lesion and will begin utilizing DES technology as a means of prevention via the treatment of lesions that are less than 60 percent stenosed. This phenomenon, combined with the fact that interventional cardiologists

will perform more multi-vessel procedures, suggests strongly that CMS's assumption of 1.5 DES devices per case is a gross underestimation – specifically when we consider that past utilization of 1.5 stents per case has been typically related to a single lesion.

Salient Observations – Past Practice:

1. *Among percutaneous coronary intervention (PCI) patients, one-quarter are diabetic and one-third have had previous PCI procedures and/or coronary artery bypass grafting (CABG).* Diabetes is the single most prevalent presenting comorbidity despite mixed clinical results in these patients. Fully one-third of patients has had a previous PCI, whereas only 20 percent have had previous CABG. Other important findings: average ejection fraction is over 50 percent; fewer than 15 percent have peripheral vascular disease.
2. *Vast majority of procedures – fully 90 percent – provides revascularization in only one vessel.* Nearly half of PCI patients present with significant disease (≥ 50 percent stenosis) in two and three vessels, yet all but 10 percent have only a single vessel intervened on. Less than one percent of PCI cases are three-vessel interventions.
3. *Virtually no Left Main disease treated, primary lesion located equally in LAD and RCA/PDA arteries.* Intervention on the left main artery is infrequently performed in the catheterization laboratory, this disease overwhelmingly referred for CABG. Forty percent of primary lesions are located in the LAD artery, 40 percent in the RCA/PDA vessels, and 20 percent in the Circumflex artery.
4. *Average PCI patient presents with 2.7 diseased lesions, but only has 1.4 lesions treated.* Data support conventional interventional practice of treating only those lesions that appear to significantly compromise functional capabilities of the patient. As such, “full revascularization” (i.e., treating all lesions with ≥ 50 percent stenosis) has not been an objective of percutaneous intervention.

These observations are drawn from a review of historical practice and with the understanding that physicians have only had access to traditional bare-metal stents. With DES technology, past practice will immediately become null and void. DES technology, with its essential zero (0) percent restenosis rates, will change the practice of interventional cardiology overnight. Moreover, utilization of DES per case is likely to mirror or exceed the experience in Europe. Utilization of DES per case in Europe has been approximately 2.2 +/- 1.4.

Experts suggest that DES technology will achieve rapid adoption for three reasons: 1) physicians are extremely excited about this technology due to its proven clinical efficacy, 2) patients are already demanding the technology based upon positive reports in the media, and 3) CMS has provided some mitigation of the reimbursement risk associated with the technology in its 2003 IPPS proposal. If utilization in the United States achieves parity with (or exceeds) utilization of DES per case in Europe, current reimbursement provisions will not be enough to cover the cost of the technology. As such, DRGs 526 and 527 require further upward adjustment based upon data from Europe and projected utilization per case at institutions in the United States.

Implantable Cardioverter-Defibrillators

Experts are projecting that the utilization of ICDs will increase by as much as 40 percent in the future. This projection is made due to findings in the recently published MADIT II trial (Moss AJ. *N Engl J Med.* 2002; 346:877-83) which showed life-saving benefit of prophylactic ICD implantation in patients with an ejection fraction of less than 30 percent and a previous myocardial infarction. The FDA has accepted the findings of MADIT II as appropriate for implantation of an ICD. The American College of Cardiology and the North American Society for Pacing and Electrophysiology have edited MADIT II criteria into their guidelines for ICD implantation. However, CMS has yet to accept these findings as valid for reimbursement of an ICD implant.

CMS has seemingly suggested that based upon the general difficulty of predicting which patients will actually benefit from prophylactic implantation of an ICD – even when the patient meets MADIT II criteria – it will not reimburse for any implants that are done for these reasons. This is most unfortunate, as ICD therapy has clearly been proven to save lives in the population of patients in question. Moreover, CMS has allowed local intermediaries the ability to approve/disapprove reimbursement for ICD implants for MADIT II criteria, thereby enabling uneven application of reimbursement on a national basis. This uneven application of reimbursement to implant procedures undertaken for valid clinical reasons (as approved by the FDA) has caused much frustration amongst the hospital and physician community.

Current reimbursement criteria for ICD implantation are as follows:

1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause;
2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.

As noted, these indications, while still valid individually, are not consistent with currently available clinical findings regarding ICD implantation and are therefore outdated based upon current information published in recent literature. Therefore, CMS should take seriously the advice of its recently convened Medicare Advisory Committee and approve an expansion of reimbursement criteria for ICD implantation to include MADIT II criteria, along with any other relevant and appropriate indications for ICD implantation (specifically Congestive Heart Failure).

Conclusions

The ACCA/AAMA formally recommends that CMS enhance reimbursement for drug-eluting stent procedures to reflect utilization levels that are presently occurring in Europe and are likely to be present here in the United States. The ACCA/AAMA further encourages CMS to expand reimbursement criteria for implantable cardioverter-defibrillators to include MADIT II criteria

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and other relevant indications such that this therapy can be offered to patients without worries of adequate reimbursement.

The ACCA members' primary goal is to improve access and delivery of cardiovascular patient care through the diagnosis and treatment of patients with various forms of cardiovascular diseases. We are concerned that adoption and subsequent utilization of drug-eluting stents will greatly outpace CMS's originally proposed reimbursement. We are also concerned about the inconsistent availability of reimbursement for ICD implants undertaken for MADIT II criteria and the inevitable increase in ICD implant volumes without assurance of sufficient reimbursement to cover the provision of these services. Inadequate and/or unavailable reimbursement for these services will make it difficult for cardiovascular programs to successfully offer these services and continue to meet the continuous demands placed upon them.

Again, we appreciate the opportunity to provide preliminary commentary to the impending CMS IPPS proposal. We remain fully supportive of prospective payment for hospital inpatient services, and commend CMS for its precedent-setting move related to drug-eluting stents as a part of the 2003 IPPS. However, we firmly believe that it is critical that CMS' payment rates be established in such a way that actual utilization trends are taken fully into account. We are committed to working with CMS and other affected parties to ensure that hospitals remain able to provide access to high quality cardiovascular care involving cutting-edge technologies like drug-eluting stents and implantable cardioverter-defibrillators. We look forward to working with you to provide Medicare beneficiaries continued access to high quality, efficient, and effective cardiovascular services.

Sincerely,

R. Kyle Kramer, FAAMA, FACCA
President, ACCA

*the American College of Cardiovascular Administrators
is a specialty group of the
American Academy of Medical Administrators*

Xc: Renee Schleicher, CAE
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