January 3, 2011

Via Electronic Mail
Donald M. Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1504-P
P.O. Box 8013
Baltimore, Maryland 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations (CMS-1504-FC)

Dear Dr. Berwick:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations (CMS-1504-FC) (Federal Register, Vol. 75, No. 226, Wednesday, November 24, 2010, p. 71800).

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed understands the complexity of the OPPS payment methodology and appreciates the considerable effort you and your staff have devoted to the development of the final CY 2011 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) rule. While we are pleased with some of the proposed changes, we remain concerned with others and welcome the opportunity to provide comments on the following issue:
I. Updates Affecting OPPS Payments
   A. Recalibration of APC Relative Weights—Data Development Process and Calculation of Median Costs
      i. Calculation of Single Procedure APC Criteria-Based Median Costs for Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)

I. Calculation of Single Procedure APC Criteria-Based Median Costs for Endovascular Revascularization of the Lower Extremity

AdvaMed has a number of comments related to the interim CY 2011 APC assignment for the following CPT codes:

- 37221 - Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement (s), includes angioplasty within same vessel, when performed

- 37223 - Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement (s), including angioplasty within the same vessel, when performed

These CPT codes were approved by the AMA for inclusion in the CPT code book/use effective January 1, 2011. The new codes represent endovascular revascularization procedures that were previously billed using separate procedure codes that were housed within different APCs. Following the review of simulated median cost data for the procedures, CMS assigned CPT codes 37221 and 37223 to APC 0083. Per CMS OPPS data files, the approximate median cost of procedures within APC 0083 is $3,740.

AdvaMed appreciates CMS’ willingness to develop an alternative rate setting approach for these newly created codes. The method tries to capture the resources consumed for the various combinations of peripheral interventions. While we believe the alternative method represents a positive step toward ensuring that Medicare payment aligns more closely with the costs of these endovascular services, AdvaMed has concerns regarding the placement of CPT codes 37221 and 37223 in APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty).

AdvaMed believes that the codes are more appropriately classified in APC 0229 (Transcatheter Placement of Intravascular Shunt and Stents) and recommends that CMS consider their immediate reassignment to APC 0229, possibly as part of a 2011 quarterly update.

While both CPT codes 37221 and 37223 have a non-coronary angioplasty component, both procedures describe the transcatheter placement of an intravascular stent, making assignment to APC 0229 a much better fit from the standpoint of clinical similarity. Additionally, the median costs and resource similarity of CPT codes 37221 and 37223 more closely match the resources of procedures in APC 0229 than those in APC 0083.

The assignment of these codes to APC 0229 is further supported by an external analysis of Medicare claims data performed by Chris Hogan of Direct Research LLC which looks at the median cost of
these procedures. Targeting the claims of the predecessor CPT codes for 37221 (37205 and 35473), the analysis reveals a median cost of $9,042, which aligns with CMS' published median costs for 37226 (stent placement femoral/popliteal $9,600) and 37230 (stent placement tibial/peroneal $7,868) which both map to APC 0229. It is important to note that AdvaMed’s analysis of median costs required the inclusion of the iliac angioplasty code of 35473 whereas Table 7 of the Final Rule indicates that the angioplasty code was optional. We believe this distinction results in the disparate median costs calculations.

Additionally, APC 0229 contains eleven codes including seven stent procedure codes. CPT codes 37221 and 37223 both include stent placement with angioplasty. As a device-intensive procedure, CPT code 37221 is more clinically aligned with APC 0229 which includes other device-intensive peripheral stenting interventions. Because CPT code 37223 describes an add-on iliac stent procedure for each ipsilateral iliac vessel, this code should also be reassigned to APC 0229, consistent with the APC assignments for CPT code 37205 (peripheral stenting) and its add-on procedure code 37206 (peripheral stenting, each additional vessel).

Conversely, the procedures in APC 0083, include balloon angioplasty, arterial repairs, and other much less device-intensive procedures than those described by CPT codes 37221 and 37223. Moreover, APC 0083’s median cost ($3,740) is only about half the median cost of CPT code 37221 ($6,710). Clearly, CPT 37221 more closely aligns with the median cost of APC 0229 ($7,940).

Finally, inclusion of CPT code 37221 and its add-on code 37223 in APC 0083 means the payment rate for these services will fall far short of the median cost ($6,710 for CPT 37221) of these procedures. AdvaMed is concerned that this classification conflicts with the principles underlying the APC system, namely grouping resource and clinically similar procedures within the same APC in an effort to reduce dramatic swings in payment. Moving CPT codes 37221 and 37223 into APC 0083 creates both a significant and dramatic change in the payment for these procedures. Additionally, moving the codes into APC 0083 has created a two times rule violation within the APC. In order to resolve the problems created by placing CPT codes 37221 and 37223 into APC 0083, AdvaMed again recommends that CMS move these codes into APC 0229, a more clinically and resource similar APC.

Conclusion

AdvaMed greatly appreciates the opportunity to comment on the CY 2011 OPPS and ASC final rule with comment and urges CMS to consider and incorporate our recommendations. We also urge CMS to give consideration to comments from AdvaMed members and others who will be providing recommendations on these issues.

We would be pleased to answer any questions regarding these comments. Please contact DeChane L. Dorsey, Esq., Vice President, Payment and Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

Ann-Marie Lynch
Executive Vice President,
Payment and Health Care Delivery