

The Society for Cardiovascular Angiography and Interventions

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June 25, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1588-P
P.O. Box 8011
Baltimore, MD 21244-1850

Submitted electronically via http://www.regulations.gov

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year (FY) 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; 77 Fed. Reg. 27, 870 (May 11, 2012); CMS–1588–P; RIN 0938–AR12

Dear Ms. Tavenner:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 4,000 members representing the majority of practicing interventional cardiologists in the United States. SCAI promotes excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care. SCAI having reviewed the "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year (FY) 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; 77 Fed. Reg. 27,870 (May 11, 2012); CMS–1588–P; RIN 0938–AR12" offers the following clinical guidance in regards to DRG assignments for percutaneous mitral valve repair with implant and the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft.

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Percutaneous Mitral Valve Repair With Implant

Per the proposed rule, CMS received request to reassign code 35.97 (Percutaneous mitral valve repair with implant) to the following MS–DRGs:

- MS–DRG 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with MCC);
- MS-DRG 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with CC);
- MS–DRG 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac without CC/MCC);
- MS–DRG 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with MCC);
- MS-DRG 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with CC); and
- MS–DRG 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac without CC/MCC).

SCAI, representing the majority of physicians with clinical expertise in the performance of, typical patient population treated, and hospital resources used for percutaneous mitral valve repair with implant, strongly supports this proposed reassignment to MS-DRGs: 216-221, which are much more closely aligned in regards to clinical homogeneity and hospital resource use than the existing DRG assignments. The hospital resources used in the performance of percutaneous mitral valve repair with implant including procedure setting, physicians' involvement, operating room ancillary staff utilized, the requirement of general anesthesia, and technology requirements are most similar to other valve repair and replacement procedures. The current DRG assignment, which include procedures such as balloon valvuloplasty and percutaneous transluminal coronary angioplasty (PTCA) are just not as similar in regards to intensity and resulting resource consumption. SCAI is concerned that there is a lack of appropriate and adequate reimbursement for new technologies such as percutaneous mitral valve repair with implant.

SCAI does not support CMS' proposal to retain the current DRG assignment for 35.97 (Percutaneous mitral valve repair with implant), which CMS claims is now being based on the cost analysis of only 39 claims. The device used for percutaneous mitral valve repair with implant is still in clinical trial which typically supports only coverage for routine costs. SCAI believes many providers may not be accurately capturing and/or reporting the actual costs for these procedures and urges CMS to focus on clinical homogeneity with comparison of hospital resource use to other clinically similar services in regards to DRG assignment.

SCAI urges CMS to reassign code 35.97 (Percutaneous mitral valve repair with implant) to MS-DRGs: 216-221; finding these DRGs to be more similar in regards to clinical homogeneity and hospital resource use than the current DRG assignment which results in an inadequate level of reimbursement for this new technology.

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Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

Per the proposed rule, CMS received request to reassign code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) from MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) as these DRGs are much more closely aligned in regards to clinical homogeneity and hospital resource use than the existing DRG assignments.

The fenestrated graft device is significantly larger than the stents used in the procedures associated with the current DRG assignment. Fenestrated graft devices typically involve an open vascular cut-down to facilitate insertion and passage of the device. The stents used in the procedures associated with the current DRG assignment do not necessitate open vascular cut-down and are typically advanced through percutaneous access. Per the proposed rule, the typical patients receiving these devices are "predominantly contraindicated for open repair. ...[as] Open surgical repair is too challenging to frail patients, as it requires supraceliac clamping of the aorta and may result in renal ischemia, mesenteric ischemia, or atheroembolization of the visceral vessels of the aorta."

Per Medicare utilization data as presented in the AMA RUC database, only 36 of these cases were reported in 2011. SCAI finds that there is insufficient claims data to determine cost and therefore, CMS should rely on clinical homogeneity with comparison of hospital resource use to other clinically similar services in regards to DRG assignment. Code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) represents an aortic aneurysm repair procedure and as with all other aortic aneurysm repair procedures 38.78 should be placed in MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively).

SCAI urges CMS to reassign code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) to MS-DRGs 237 and 238; finding these DRGs to be more similar in regards to clinical homogeneity and hospital resource use than the current DRG assignment which results in an inadequate level of reimbursement for this new technology.

SCAI appreciates the opportunity to provide comment to CMS regarding the valuation of interventional cardiology services under the "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year (FY) 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; 77 Fed. Reg. 27,870 (May 11, 2012); CMS–1588–P; RIN 0938–AR12". If SCAI can be of any further assistance in providing clinical expertise and guidance in regards to the DRG assignment for interventional cardiology procedures, now or in the future, please do not hesitate to contact Ms. Dawn R. Hopkins, Director of Reimbursement & Regulatory Affairs at (800) 253-4636, ext. 510 or dhopkins@scai.org.

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Sincerely

J. Jaffrey Marshall, MD, FSCAI SCAI President, 2012-2013

CC: James Blankenship, MD, SCAI Norm Linsky, SCAI Wayne Powell, SCAI

Joel Harder, SCAI Dawn R. Hopkins, SCAI