

Chairman of the Board
William H. Roach, Jr., Esq

President
Gordon F. Tomaselli, MD, FAHA

Chairman-elect
Ron W. Haddock

President-elect
Donna K. Arnett, PhD, BSN, FAHA

**Immediate Past
Chairman of the Board**
Debra W. Lockwood, CPA

Immediate Past President
Ralph L. Sacco, MD, FAHA

Secretary-Treasurer
Bernard P. Dennis

Directors
Joyce Beatty, MS
David A. Bush
Mark A. Creager, MD, FAHA
Shawn A. Dennis
Barry A. Franklin, PhD, FAHA
Max Gomez, PhD
Mariell Jessup, MD, FAHA
John J. Mullenholz
Janet Murguía
James J. Postl
Alvin L. Royse, JD, CPA
David A. Spina
Bernard J. Tyson
Henry J. Wasiak, MBA

Chief Executive Officer
Nancy A. Brown

Chief Mission Officer
Meighan Girgus

**Chief Administrative Officer &
Chief Financial Officer**
Sunder D. Joshi

Chief Science Officer
Rose Marie Robertson, MD, FAHA

Chief Development Officer
Suzie Upton

**Executive Vice President
Communications**
Matthew Bannister

**Executive Vice President
Corporate Secretary &
General Counsel**
David Wm. Livingston, Esq

**Executive Vice President
ECC Programs**
John Meiners

**Executive Vice President
Consumer Health**
Kathy Rogers

**Executive Vice President
Advocacy & Health Quality**
Mark A. Schoeberl

**Executive Vice President
Technology & Customer Strategies**
Michael Wilson



October 28, 2011

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00430N

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) national coverage analysis for transcatheter aortic valve replacement (TAVR).

CMS opened the coverage analysis after receiving a joint request from the American College of Cardiology (ACC) and the Society for Thoracic Surgery (STS). The organizations have asked CMS to develop a coverage policy for TAVR to ensure that the technology is used appropriately in the Medicare population. According to the ACC and STS request, the organizations believe that a transcatheter device for aortic valve implementation may soon receive Food and Drug Administration (FDA) approval.

If a TAVR device is approved by the FDA, AHA recommends that CMS add coverage of this procedure to the Medicare program. TAVR represents a reasonable treatment option for patients with severe aortic valve stenosis who are considered high risk candidates for traditional surgical aortic valve replacement. TAVR also presents an alternative for inoperable patients who would otherwise be treated with medical therapy.

TAVR, however, is a relatively new technology in the United States and to date has been limited to physician investigators in centers of excellence within clinical trials. Therefore, it may be appropriate for CMS to limit Medicare coverage, as ACC and STS recommend, to specialized heart centers that utilize a modified conventional cardiac laboratory or hybrid operating room that contains the specialized equipment necessary for the procedure. TAVR should also be performed by appropriately trained, integrated multidisciplinary teams.

In addition, we support requiring facilities that perform TAVR to report data to a national registry. A clinical registry will facilitate comprehensive data collection, ensure that the appropriate patients receive this therapy, and allow for a review of patient outcomes. A registry will also provide CMS with data that may support expanding Medicare coverage of this procedure at a later date.

In closing, we reiterate our support for adding TAVR to the Medicare program if a device receives FDA approval. If this occurs, we recommend that CMS limit coverage to patients considered inoperable or patients for whom traditional aortic valve replacement carries a high surgical risk. CMS should also limit the procedure to facilities where operators and infrastructure elements are appropriate. Facilities that perform the procedure should be required to participate in a national registry.

Thank you for consideration of our comments. If you have any questions or require any additional information, please contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Sincerely,

A handwritten signature in blue ink, appearing to read 'G. Tomaselli', with a long horizontal flourish extending to the right.

Gordon F. Tomaselli, MD, FAHA
President
American Heart Association