

**MEETING MINUTES
OF THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES
MEDICARE EVIDENCE DEVELOPMENT & COVERAGE
ADVISORY COMMITTEE**

November 14, 2012

**Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland**

Medicare Evidence Development & Coverage Advisory Committee

November 14, 2012

Attendees

Chairperson

Rita Redberg, MD, MS

Vice-Chair

Art Sedrakyan, MD, PhD

Voting Members

Ralph Brindis, MD, MPH, MACC

Raymond E. Faught, Jr., MD

Mark D. Grant, MD, MPH

Peter Heseltine, MD

Curtis Mock, MD, MBA

Jeffrey B. Rich, MD

J. Sanford Schwartz, MD

Robert L. Steinbrook, MD

Industry Representative

Shamiram R. Feinglass, MD, MPH

Guest Panel Members

G. Kevin Donovan, MD, MA

Robert Kormos, MD

Ileana L. Pina, MD, MPH, FAHA, FACC

Invited Guest Speakers

Keith Aaronson, MD

James Kirklin, MD

David C. Naftel, PhD

Lynne Warner Stevenson, MD

CMS Liaison

Jyme Schafer, MD

Executive Secretary

Maria Ellis

Wednesday, November 14, 2012, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on November 14, 2012, to discuss the evidence, hear presentations and public comment, and make recommendations concerning the use of ventricular assist devices, VADs, as clinical strategy for the management of heart failure.

The meeting began with a reading of a conflict of interest statement, welcoming remarks, and an introduction of the Committee.

CMS Presentation and Voting Questions. A CMS representative informed the panel and audience of the current national coverage policy regarding VADS, explained some of the definitions that would be used during the discussion and voting, and then read the voting and discussion questions that would be considered by the panel.

Presentations by Invited Guest Speakers. The panel heard presentations from the four invited guest speakers and one invited guest panel member. Dr. Stevenson gave an overview of heart failure, its classification systems, complexity of medical therapy and options for treatment as it progresses. Dr. Kormos explained the terminology and classification of mechanical support devices. Dr. Aaronson presented an overview of completed and planned studies on circulatory support devices. Dr. Naftel offered an introduction to the INTERMACS registry, followed by Dr. Kirklin giving a current overview of the registry results. Dr. Stevenson then offered the committee an overview of how heart failure cardiologists approach decision making for individual patients. Following the presentations, the panel posed limited questions to the presenters.

Scheduled Public Comments. Following a break, the panel heard from a total of seven scheduled speakers, including representatives from professional societies and clinicians.

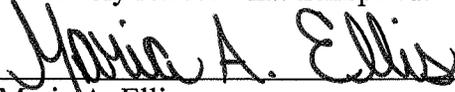
Open Public Comments. The panel heard from four members of the public.

Questions to Presenters. The panel participated in a lengthy discussion and question and answer session with all of the presenters.

Initial Open Panel Discussion, Formal Remarks and Voting Questions. The panel turned its attention to the voting questions, having limited additional discussion before votes on each question. The results of the voting were recorded on electronic devices and recorded manually, announced to the public, and were recorded by CMS staff. Following each voting question, the panelists focused on the discussion questions, comments on which are found in the transcript.

Adjournment. The meeting adjourned at 3:25 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development
& Coverage Advisory Committee on
November 14, 2012, and that these minutes
accurately reflect what transpired.



Maria A. Ellis
Executive Secretary, MEDCAC, CMS

I approve the minutes of this meeting
as recorded in this summary.



Rita Redberg, MD, MS
Chairperson