

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

March 22, 2017

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

Medicare Evidence Development & Coverage Advisory Committee

March 22, 2017

Attendees

Chairperson

Rita Redberg, MD, MSC

Acting Vice Chairperson

Alan Hirsch, MD

MEDCAC Members

Salvador Cruz-Flores, MD, MPH
Michael J. Fisch, MD, MPH, FACP
Fred Kobylarz, MD, MPH
Marcel Salive, MD, MPH
Art Sedrakyan, MD, PhD
Jodi B. Segal, MD, MPH
Julie Ann Swain, MD
Diana Zuckerman, PhD

Representatives

Eileen Hsich, MD
Lynne Warner Stevenson, MD

Industry Representative

Adi Renbaum, MBA

Guest Panel Members

Elise Berliner, PhD
Patrice Desvigne-Nickens, MD
Clyde W. Yancy, MD, MSc, MACC, FAHA
Bram Zuckerman, MD

Invited Guest Speakers

Philip B. Adamson, MD, Msc, FACC
Larry A. Allen, MD, MHS
John D. Carroll, MD
William Lawrence, MD
Ileana L. Pina, MD, MPH

CMS Liaison

Joseph Chin, MD

Executive Secretary

Maria Ellis

Wednesday, March 22, 2017, 8:07 a.m.

The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) met on March 22, 2017, to discuss recommendations regarding what health outcomes and studies for heart failure treatment technology should be of interest to CMS.

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 presented information addressing the goals of today's meeting, summarized the current FDA processes for approving heart failure treatment technology, mentioned some of the endpoints used to define meaningful health outcomes by international organizations, defined the terms applicable for the meeting and the panel's consideration of the questions, and then read the voting and discussion questions that would be considered by the panel.

Presentation by Invited Guest Speakers. The panel heard presentations from the invited guest speakers. Dr. Pina discussed the treatment goals of the patient and physician from a clinical point of view, asserting that both hospitalizations and hospitalization equivalent events should be outcomes in heart failure. She also stressed the importance of getting patients on guideline-directed medical and exercise therapies. Dr. Adamson addressed the subject of heart failure treatment and outcomes from the perspective of AdvaMed, a group representing industry, focusing on patient-centric outcome measures. Dr. Carroll addressed the subject from the perspective of an interventional cardiologist. Dr. Lawrence and Dr. Allen discussed some of the work of PCORI, particularly in patients with LVAD.

Scheduled Public Comments. The panel heard from a total of six scheduled speakers, including society and industry representatives. These speakers informed the committee of current and planned trials related to heart failure trial outcomes and endpoints, summarized some of their clinical and research experience, and addressed the use of surrogate or intermediate endpoints.

Open Public Comments. Three members of the general public addressed the panel, including a representative from a heart failure support group, an industry representative, and a heart failure patient.

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

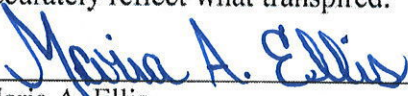
Initial Open Panel Discussion, Formal Remarks and Voting Questions. The panel conducted an in depth discussion of the issues raised, before turning its attention to the voting questions.

Before voting, Dr. Redberg informed the audience that question 2.b had been changed to consider degenerative and functional mitral regurgitation separately. Thus, question 2.b considered degenerative mitral regurgitation, a new question 2.c considered functional regurgitation, and the original question 2.c was remarked 2.d. Further, question 4.b was modified, deleting the phrase "included as." Question 4.c was also modified, deleting the word "standalone." The results of the voting were recorded on electronic devices, recorded manually, announced to the public, and were recorded by CMS staff. Following the voting questions, the panelists focused on the discussion portion of questions one and two, comments on which are found in the transcript.

Final Open Panel Discussion. The panel commented on the additional discussion topics, which are recorded in the transcript.

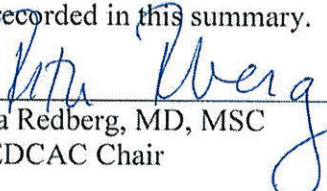
Adjournment. The meeting adjourned at 3:55 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development
and Coverage Advisory Committee on
March 22, 2017, 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, MSC
MEDCAC Chair