

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

July 20, 2016

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

Medicare Evidence Development & Coverage Advisory Committee

July 20, 2016

Attendees

Chairperson

Rita Redberg, MD, MSC

Acting Vice Chairperson

Art Sedrakyan, MD, PhD

Voting Members

Doug Campos-Outcalt, MD, MPA

John Jeffrey Carr, MD

Aloysius B. Cuyjet, MD, MPH

Peter F. Lawrence, MD

Roger J. Lewis, MD, PhD, FACEP

Sandra J. Lewis, MD, FACC

Marcel Salive, MD, MPH

Diana Zuckerman, PhD

Industry Representative

Leslie Wise, JD

Guest Panel Members

Teresa L. Carman, MD

Anthony J. Comerota, MD, FACS, FACC

Invited Guest Speakers

Matthew Allison, MD, MPH, RPVI

Fedor Lurie, MD, PhD, RPVI

Thomas Wakefield, MD

CMS Liaison

Lori Ashby, MA

Executive Secretary

Maria Ellis

Wednesday, July 20, 2016, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on July 20, 2016, to discuss the evidence, hear presentations and public comment, and to make recommendations concerning treatment strategies for patients with lower extremity chronic venous disease, and evidence gaps surrounding this area.

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 regarding the purpose of today's meeting, described the outcomes of interest to CMS, gave a definition of 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 Speaker. The panel heard a presentation from Dr. Allison discussing the anatomic micropathology of the venous system, how various disease conditions of the veins or valves can affect blood flow, causing symptoms and signs leading to varying levels of chronic venous insufficiency.

TA Presentation. Doctors Jones and Vellumapalli presented the results of a technology assessment conducted by the Duke University Medical Center looking at the evidence on treatment strategies for patients with lower extremity chronic venous disease.

Presentations by Invited Guest Speakers. The panel heard presentations from the two remaining invited guest speakers. Dr. Wakefield discussed the potential use of registries for obtaining additional data in the real world, and highlighted the efforts of the Vascular Quality Initiative. Dr. Lurie discussed the integrated systematic process developed by the American Venous Forum Foundation to address gaps in identification, efforts to collect evidence to address those gaps, and to synthesize them into practice guidelines.

Scheduled Public Comments. The panel heard from a total of 23 scheduled speakers, including society and coalition representatives, practitioners, and industry representatives. These speakers informed the committee of current and planned trials related to lower extremity chronic venous disease, and summarized some of their clinical experiences.

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 turned its attention to the voting questions, conducting a discussion among the panelists before voting. 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 4:14 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development
and Coverage Advisory Committee on
July 20, 2016, 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