

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

July 22, 2015

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

Medicare Evidence Development & Coverage Advisory Committee

July 22, 2015

Attendees

Vice Chairperson

Peter Bach, MD, MAPP

Voting Members

Doug Campos-Outcalt, MD, MPA

John Jeffrey Carr, MD

Aloysius B. Cuyjet, MD, MPH

Richard A. Deyo, MD, MPH

Peter F. Lawrence, MD

Frank V. Lefevre, MD

Sandra J. Lewis, MD, FACC

Marcel Salive, MD, MPH

Julie Ann Swain, MD

Diana Zuckerman, PhD

Representative

Robert L. Kormos, MD, FRCS(C), FACS

Industry Representative

Theodore C. Lystig, PhD

Guest Panel Member

Alan T. Hirsch, MD

Invited Guest Speakers

Jack L. Cronenwett, MD

Matthew T. Menard, MD

CMS Liaison

Tamara Syrek Jensen, JD

Executive Secretary

Maria Ellis

Wednesday, July 22, 2015, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on July 22, 2015, to discuss the evidence, hear presentations and public comment, and to make recommendations concerning treatment of lower extremity peripheral artery 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.

TA Presentation. Doctors Jones and Patel presented the results of a technology assessment conducted by the Duke University Medical Center looking at the evidence on treatment strategies for patients with peripheral artery disease.

Presentations by Invited Guest Speakers. The panel heard presentations from the two invited guest speakers. Dr. Cronenwett discussed the use of registries for obtaining additional data in the real world, and highlighted the efforts of the Vascular Quality Initiative. Dr. Menard presented the panel with an overview of the NIH sponsored BEST-CLI trial.

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

Questions to Presenters. The panel participated in a lengthy discussion and question and answer session with 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, discussing questions and concerns 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 questions, comments on which are found in the transcript.

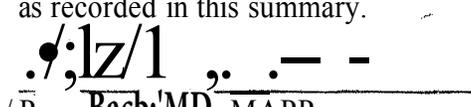
Adjournment. The meeting adjourned at 3 :53 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development
& Coverage Advisory Committee on
July 22, 2015, and that these minutes
accurately reflect the proceedings.



Maria X. Ellis
Executive Secretary, MEDCAC, CMS

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



P. Bach, MD, MAPP
Vice Chair