

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

January 30, 2013

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

Medicare Evidence Development & Coverage Advisory Committee

January 30, 2013

Attendees

Chairperson

Rita Redberg, MD, MS

Vice-Chair

Art Sedrakyan, MD, PhD

Voting Members

Jeffrey W. Cozzens, MD, FACS

Raymond E. Faught, Jr., MD

A. Mark Fendrick, MD

Steven Gutman, MD

Paula E. Hartman-Stein, PhD

Susan A. Levine, DVM, MS, PhD

Theresa Miskimen, MD

Curtis Mock, MD, MBA

Jerrold Rosenbaum, MD

Amy E. Sanders, MD, MS

Robert K. Zeman, MD

CMS Liaison

Louis Jacques, MD

Industry Representative

Brian Seal, RPh, MBA, PhD

Guest Panel Members

Peter Herscovitch, MD

Constantine G. Lyketsos, MD, MHS

Invited Guest Speakers

Paul Aisen, MD

Randall J. Bateman, MD

Mark Mintun, MD

Steven D. Pearson, MD, MSc, FRCP

William Thies, MD

Executive Secretary

Maria Ellis

Wednesday, January 30, 2013, 8:09 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on January 30, 2013, to discuss the evidence, hear presentations and public comment, and make recommendations concerning beta amyloid positron emission tomography in dementia and neurodegenerative disease.

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 purpose of the meeting, gave an overview of current and predicted statistics regarding Alzheimer's disease, and the current national coverage policy regarding the use of amyloid PET. Another representative explained 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 five invited guest speakers. Dr. Aisen provided a background of dementia and Alzheimer's disease and the goals of amyloid PET scanning. Dr. Bateman presented the clinical and biomarker changes in Alzheimer's disease. Dr. Pearson summarized the research and literature reviewed by The Institute for Clinical and Economic Review resulting in a white paper titled Diagnostic Tests for Alzheimer's Disease Generating and Evaluating Evidence to Inform Insurance Coverage Policy. Dr. Thies presented the views of the Alzheimer's Association and summarized the appropriate use guidelines developed by the Association in concert with the Society for Nuclear Medicine and Molecular Imaging. Dr. Mintum summarized the efforts of Avid Radiopharmaceuticals during the FDA approval process, and summarized ongoing research being undertaken.

Scheduled Public Comments. Following a break, the panel heard from a total of eleven scheduled speakers who had submitted comments to the committee, including representatives from professional societies, manufacturers, researchers and clinicians.

Open Public Comments. The panel heard from two members of the public who had not previously submitted comments.

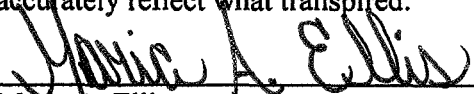
Questions to Presenters. The panel participated in a lengthy discussion and question and answer session with all of the presenters.

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 explained their rationale for the votes. The panel then

turned their attention to the discussion questions, comments on which are found in the transcript.

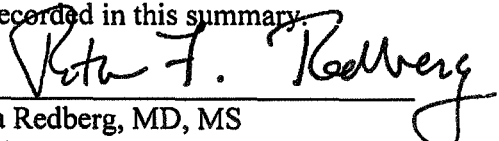
Adjournment. The meeting adjourned at 3:09 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development
& Coverage Advisory Committee on
January 30, 2013, 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