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

March 21, 2012

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

Medicare Evidence Development & Coverage Advisory Committee

March 21, 2012

Attendees

Chairperson
Clifford Goodman, PhD

Vice-Chair
Steve E. Phurrough, MD

Voting Members
Wendolyn S. Gozansky, MD, MPH
Peter Heseltine, MD
Susan A. Levine, DVM, MS. PhD
Pamela R. Massey, PT, MS
Robert McDonough, MD, JD
Prabashni Reddy, PharmD
Art Sedrakyan, MD, PhD
Robert L. Steinbrook, MD

Industry Representative
Robert W. Dubois, MD, PhD

Guest Panel Member
James E. Puklin, MD, FACS

Invited Guest Speaker
Robert N. Frank, MD

CMS Liaison
James Rollins, MD

Executive Secretary
Maria Ellis

Wednesday, March 21, 2012, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on March 21, 2012, to discuss the evidence, hear presentations and public comment, and make recommendations concerning the currently available evidence regarding the intravitreal targeted treatment of diabetic retinal disease, diabetic macular edema, DME.

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 goals for the day's meeting, 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 Speaker. The panel heard a presentation from Dr. Frank explaining diabetic retinopathy and diabetic macular edema, summarizing the history of treatment of the conditions and related studies, including means of assessment and risk stratification.

Presentation of Technology Assessments. The panel heard the results of two technology assessments. The first, presented by Dr. Donna Dryden, was the technology assessment performed under contract to AHRQ by the Evidence-Based Practice Center at the University of Alberta, primarily concerning health-related quality of life outcomes in this arena. The second, presented by Dan Ollendorf, was the technology assessment performed by the Institute for Clinical and Economic Review.

Scheduled Public Comments. The panel heard from a total of six scheduled speakers, including a manufacturer's representative, a representative from an advocacy group, three representatives from professional societies, and a clinician.

Open Public Comments. The panel heard from four members of the public, including another manufacturer's representative, and representatives from three patient advocacy groups, including one who has diabetes and AMD.

Questions to Presenters. The panel participated in an extensive discussion focused on the voting and discussion questions, including follow-up discussion of particular relevant issues with all of the presenters.

Initial Open Panel Discussion. The panel then focused its comments and inquiry on discussion question one. This discussion included input from the chair, members of the panel, and presenters as requested by members of the panel.

Formal Remarks and Voting Questions. The panel turned its attention to the voting questions, having focused 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.

Final Open Panel Discussion. After addressing the voting questions, the panel turned its attention to the final three discussion questions, receiving, again, comments from panel members and presenters. Following that, each panelist was asked to express his or her opinion regarding, either for the Medicare program or for other stakeholders in the management of DME, the single most important finding or observation that stakeholders should have taken from the day's meeting. That discussion and those statements are contained in the transcript of the meeting.

Adjournment. The meeting adjourned at 3:51 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on March 21, 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.

Clifford Goodman, Ph.D.
Chairperson