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

January 19, 2011

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

Medicare Evidence Development & Coverage Advisory Committee

January 19, 2011

Attendees

Clifford Goodman, PhD
Chairperson

Saty Satya-Murti, MD, FANN
Vice-Chairperson

Maria A. Ellis
Executive Secretary

Voting Members
René Cabral-Daniels, JD, MPH
Roger Dmochowski, MD
Leslie Grammer, MD
Roger D. Klein, MD, JD
David M. Mintzer, MD
David J. Samson, MS
Ajay Singh, MBBS, FRCP, MBA
Robert L. Steinbrook, MD

Industry Representative
Lester D. Paul, MD, MS

Guest Panel Members
Jerry A. Holmberg, MD
David Stroncek, MD

CMS Liaison
James Rollins, MD

Invited Guest Speakers
James Bowman, MD
Jeffrey L. Carson, MD
J. Michael Cecka, PhD

Wednesday, January 19, 2011, 8:11 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on January 19, 2011, to discuss the evidence, hear presentations and public comment, and make recommendations concerning currently available evidence regarding the the effects of erythropoiesis-stimulating agents (ESAs) on health outcomes in adult chronic kidney disease (CKD) patients, including predialysis and dialysis.

The meeting began with a reading of a conflict of interest statement, welcoming remarks, and an introduction of the Committee.

CMS Presentation of Voting Questions. A CMS representative presented the panel and audience with an explanation of the voting scale to be used, and the voting and discussion questions that would be considered by the panel. Another CMS representative presented the panel with background of CKD and various treatment options, including transfusions and transplantation. Following the presentation, the panel had a brief period to pose questions.

Presentation of Technology Assessment. The panel heard a presentation from a representative of the University of Connecticut/Hartford Evidence-Based Practice Center of their technology assessment performed under contract to AHRQ. Following the presentation, there was brief period for the panelists to pose questions to the presenter before moving on to the presentations from the invited guest speakers.

Presentations by Invited Guest Speakers. The panel heard presentations from three invited guest speakers. Dr. James Bowman, from the Health Resources and Services Administration at HHS, provided an overview from a clinical perspective on the impact of blood transfusions and kidney transplantation. Dr. Jeffrey Carson, from UMDNJ, addressed transfusion triggers in general and how that knowledge may relate to the use of ESAs. Dr. J. Michael Cecka, from the UCLA Immunogenetics Center, addressed tests for sensitization and transplant suitability.

Scheduled Public Comments. The panel heard from a total of 16 scheduled speakers, including patients with renal disease, clinicians, professional society representatives, patient advocacy group representatives, research investigators, and representatives of ESA manufacturers.

Open Public Comments. The panel heard from one member of the public, a clinical nephrologist.

Questions to Presenters, Open Panel Discussion and Voting Questions. The panel combined questions to presenters with discussion on each of the first three pairs of voting questions posed by CMS, followed by votes on the respective questions. The panelists cast their votes using automated devices, announced them individually, and entered them in writing on separate ballot sheets, which were collected by CMS staff. The votes are recorded in the transcript.

Final Open Panel Discussion. After resolution of the voting questions, the panel discussed questions seven and eight, the non-voting questions. At the conclusion of that discussion, the chairman asked each panelist to give a one-sentence summary of the single most important suggestion they'd make to CMS or the stakeholders about improving the body of evidence to improve decision making with regard to the use of ESAs in adult patients with CKD.

Adjournment. The meeting adjourned at 4:27 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on January 19, 2011, 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