

**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 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.

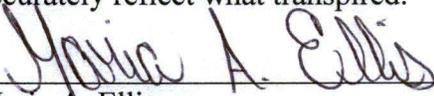
**Open Public Comments.** The panel heard from one member of the public, a clinical nephrologist.

**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.

  
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Maria A. Ellis  
Executive Secretary, MEDCAC, CMS

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



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Clifford Goodman, Ph.D.  
Chairperson