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

March 24, 2010

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

Medicare Evidence Development & Coverage Advisory Committee

March 24, 2010

Attendees

Clifford Goodman, Ph.D.
Chairperson

Saty Satya-Murti, M.D., F.A.A.N.
Vice-Chairperson

Maria A. Ellis
Executive Secretary

Voting Members
Phyllis Atkinson, R.N., M.S., GNP-BC
Virginia C. Calega, M.D., M.B.A.
Marion Danis, M.D.
Susan A. Levine, D.V.M., M.S., Ph.D.
Stephen Pauker, M.D., M.A.C.P., F.A.C.C.
Leonard M. Pogach, M.D., M.B.A., F.A.C.P.
James E. Puklin, M.D.
Robert L. Steinbrook, M.D.

Industry Representative
Eleanor M. Perfetto, Ph.D., M.S.

CMS Liaison
Louis Jacques, M.D.

Guest Panel Members
Rajiv Agarwal, M.D.
Daniel W. Coyne, M.D.
Joseph M. Messana, M.D.

Guest Speakers
Thomas MaCurdy, Ph.D.
Jerry A. Holmberg, Ph.D.
Ajay Singh, M.B.B.S., F.R.C.P., M.B.A.

Wednesday, March 24, 2010, 8:15 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on March 24, 2010, to discuss the evidence, hear presentations and public comment, and make recommendations concerning currently available evidence on the use of erythropoiesis stimulating agents (ESA) to manage anemia in patients who have chronic kidney 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 presented the panel and audience with the questions that would be considered and discussed or voted on by the panel. The medical officer for this panel then made a presentation providing the panelists with historical background on the coverage history of ESAs, and summarized some of the etiology, treatment and research in this area.

Presentation by Guest Speakers. The panel first heard a presentation from Dr. MaCurdy, from Acumen, on the trends regarding the use of ESAs in Medicare patients with kidney disease from 2006 through the present, and how those trends related to practice and policy implementation in that time frame. Dr. Holmberg, from the Office of Public Health and Science at HHS, offered a presentation on supply status, risk, and guidelines for blood transfusion. Dr. Singh, from Brigham and Women's Hospital and Harvard Medical School, discussed clinical management of anemia associated with treatment of chronic kidney disease in patients on dialysis and those not on dialysis.

Scheduled Public Comments. The panel heard from a total of 12 scheduled speakers, including clinicians, researchers, industry and professional society representatives, and ESA and dialysis patients and family members.

Open Public Comments. The panel heard from three members of the public, including a patient and patient advocacy representative, and two clinician researchers.

Questions to Presenters. The panel was given the opportunity to pose questions to the presenters.

Initial Open Panel Discussion. The panel conducted an extensive discussion on each of the questions posed by CMS. They addressed discussion question five prior to the voting questions. The 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 additional discussion and limited comments from the presenters before votes on each question. The results of the voting were shown to the public on cards and recorded by staff. At the direction of the chairperson, and following discussion of this matter, for question two, the panel voted separately for hemoglobin below 12, and

hemoglobin of 12 or greater. Since the only subparts of question two that received scores reflecting intermediate confidence or better related to hemoglobin below 12, that phrase was added to each part of question three. The panel again voted separately for hemoglobin below 12, and hemoglobin of 12 or greater, regarding all four parts of question 4.A, and parts B and D of question 4.B. For parts A and C of question 4.B, the panel only voted on hemoglobin of 12 or greater.

Final Open Panel Discussion. The issue of use of ESAs to reduce transfusion risk was briefly discussed at the request of a panelist, as reflected in the transcript. Following that, each panelist was given the opportunity to make a short statement in response to question six, which was intended by CMS as a non-voting question. The statements are contained in the transcript of the meeting.

Adjournment. The meeting adjourned at 4:32 p.m.

I certify that I attended the meeting of the Medicare Evidence Development and Coverage Advisory Committee on March 24, 2010, and that these minutes accurately reflect what transpired.

Michelle L Atkinson for

Maria A. Ellis
Executive Secretary, MEDCAC, CMS

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

Clifford Goodman

Clifford Goodman, Ph.D.
Chairperson