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

January 27, 2010

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

Medicare Evidence Development & Coverage Advisory Committee

January 27, 2010

Attendees

Clifford Goodman, Ph.D.
Chairperson

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

Maria A. Ellis
Executive Secretary

Voting Members
Phyllis Atkinson, R.N., M.S., GNP-BC
Catherine Eng, M.D., F.A.C.P.
John Cox, D.O., F.A.C.P.
Josef E. Fischer, M.D.
Daniel F. Hayes, M.D.
Nora A. Janjan, M.D., M.P.S.A.
Karen Kaul, M.D., Ph.D.
Karl Matuszewski, M.S., Pharm.D.
Maren T. Scheuner, M.D., M.P.H.
Steven Teutsch, M.D., M.P.H.

CMS Liaison
Louis Jacques, M.D.

Industry Representative
Peter Juhn, M.D., M.P.H.

Guest Panel Members
Elaine K. Jeter, M.D.
Elizabeth Mansfield, Ph.D.
William Pao, M.D., Ph.D.

Guest Speaker
Andrew N. Freedman, Ph.D.

Wednesday, January 27, 2010, 8:20 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on January 27, 2010, to discuss the evidence, hear presentations and public comment, and make recommendations concerning whether the results of pharmacogenomic testing affect health outcomes of patients with cancer when used as a guide for certain drug treatments.

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 lead medical officer for this panel made a presentation providing the panelists with some guidance on areas of focus that would assist CMS going forward, and summarized the recommendations from the MEDCAC panel in February of 2009 regarding this same general area.

Presentation by Guest Speaker. The panel heard a presentation from Dr. Freedman, giving an overview of this area, some of the research being conducted at NCI, some of the approaches of scientific research that NCI is funding, and some of the ways research findings are being translated into practice.

Presentation of Technology Assessment. The results of the technology assessment conducted by the Tufts-New England Medical Center Evidence-based Practice Center were presented. It was noted that following discussions between AHRQ, CMS and Tufts, it was determined that the assessment would only address CYP2D6, KRAS and BCR-ABL specifically, as well as cross-cutting methodological issues.

Scheduled Public Comments. The panel heard from a total of nine scheduled speakers, including clinicians, researchers and industry and professional society representatives.

Open Public Comments. The panel heard from two members of the public, including a patient advocacy representative and a representative of a manufacturing and research firm.

Questions to Presenters. The panel posed questions to the presenters during an extensive question and answer session.

Initial Open Panel Discussion. The panel conducted an extensive discussion on each of the questions posed by CMS. This discussion included input from the chair, members of the panel, and presenters as requested by members of the panel. During this discussion it was agreed by the panel to consider sub-question (d) of questions 1 and 2 in separate parts, considering diagnosis and monitoring separately from point mutation.

Formal Remarks and Voting Questions. The panel turned its attention to the voting questions, having additional discussion and focused 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. As discussed, the panel voted twice on question 1(d), on diagnosis and monitoring, and then on point mutation. The panel vote on question 2(d) was limited to only diagnosis and monitoring, since point mutation had not achieved an intermediate score on question 1.

Final Open Panel Discussion. The panel held discussions and offered recommendations concerning question four, which was intended by CMS as a non-voting question. The specific areas of discussion are contained in the transcript of the meeting.

Adjournment. The meeting adjourned at 3:46 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on January 27, 2010, 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