MEETING MINUTES

OF THE

CENTERS FOR MEDICARE AND MEDICAID SERVICES

MEDICARE EVIDENCE DEVELOPMENT AND COVERAGE

ADVISORY COMMITTEE

May 6, 2009

Centers for Medicare and Medicaid Services

7500 Security Boulevard

Woodlawn, Maryland

Medicare Evidence Development and Coverage Advisory Committee

May 6, 2009

Attendees

Acting Chair

Saty Satya-Murti, MD, FAAN

Panel Members

Marion Danis, MD

Nancy Davenport Ennis, BA

Mark D. Grant, MD, MPH

Daniel F. Hayes, MD

I Craig Henderson, MD

James E. Puklin, MD

Randel Richner, BSN, MPH

Maren T. Scheuner, MD, MPH

Teresa M. Schroeder, BS, MBA

John Spertus, MD, MPH, FACC

Jonathan P. Weiner, PhD

CMS Liaison

Marcel Salive, MD

Industry Representative

Eleanor M. Perfetto, PhD, MS

Guest Speaker

W. Gregory Feero, MD, PhD

Guest Panel Members

Steve Gutman, MD

Neil Holtzman, MD
Elizabeth Mansfield, PhD

Executive Secretary

Maria A. Ellis

Wednesday, May 6, 2009, 8:06 a.m.

The Medicare Evidence Development and Coverage Advisory Committee met on May 6, 2009, to discuss the evidence, hear presentations and public comments, and make recommendations concerning the requirements for evidence to determine if the use of screening genetic testing of beneficiaries without signs or symptoms of disease improves health outcomes in Medicare beneficiaries.

The meeting began with a discussion of conflict of issue matters, opening remarks by the CMS liaison and acting chair, followed by an introduction of the panel members.

CMS Presentation and Voting Questions

Sandra Jones RN and Jeffrey Roche, MD, MPH, presented the panel with the goals and agenda for the meeting and read the questions that would be discussed and voted upon by the panel.

Guest Speakers

The panel heard from two invited guest speakers, William G. Feero, MD, PhD, Chief, Genomic Healthcare Branch, National Human Genome Research Institute, National Institutes of Health, and Steven Teutsch, MD, MPH, Chief Science Officer, LA County Public Health Department. Dr. Teutsch discussed the work of EGAPP and how EGAPP looks at evaluating genomic tests for screening. Following this, both speakers responded to questions from the panel.

Scheduled Public Speakers

The panel heard from a representative of the Molecular Diagnostics Laboratory, a representative of Myriad Genetic Laboratories, Incorporated, a representative of Foley Hoag, LLP, a representative of the Cleveland Clinic, a representative of Hayes, Incorporated, a representative of the Association for Molecular Pathology, and a representative of the American College of Medical Genetics.

Open Comments

The panel was addressed by a professor from Johns Hopkins Bloomberg School of Public Health.

Questions

An extensive question and answer session was held between the panel, the presenters, and those who made comments.

Initial Panel Discussion

The panel conducted an extensive discussion prior to casting their votes.

Formal Remarks and Voting

The panel voted on the voting questions. Panelists displayed their numerical votes to be recorded by staff. Each panelist then explained the reasoning behind their vote.

Final Panel Discussion

After the voting, the panelists were asked to comment on the desirable methodologic characteristics of studies of cost-effectiveness for screening genetic tests for the prevention or early detection of illness or disability and whether the age of Medicare beneficiary population presents particular challenges that may compromise the generation and/or interpretation of evidence regarding genetic testing.

Final Remarks

Before adjourning, Dr. Salive thanked the panelists and the other participants for their efforts.

Adjournment

The meeting was adjourned at 3:53 p.m.

I certify that I attended the meeting of the MEDCAC Committee on May 6, 2009, 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.

Saty Satya-Murti, MD, FAAN

Acting Chair