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

May 1, 2013

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

Medicare Evidence Development & Coverage Advisory Committee

May 1, 2013

Attendees

Chairperson

Rita Redberg, MD, MSc

Vice-Chair

Art Sedrakyan, MD, PhD

Voting Members

David C. Beyer, MD, FACR
Mary A. Blegen, RN, PhD, FAAN
Steven Gutman, MD
David Howard, PhD
Pamela R. Massey, PT, MS
Jan Nowak, PhD, MD
James Rizzo, MD, MS
Amy E. Sanders, MD, MS
A. Oliver Sartor, MD
Eric C. Stecker, MD
Sandra L. Wong, MD, MS

CMS Liaison

James Rollins, MD, PhD

Industry Representative

Martin D. Marciniak, MPP, PhD

Guest Panel Members

Barbara Conley, MD Dorothy L. Rosenthal, MD, FIAC

Invited Guest Speakers

Barbara Conley, MD Sreelatha Meleth, PhD Dorothy L. Rosenthal, MD, FIAC Katrin Uhlig, MD, MS Nedra Whitehead, PhD, MC, CGC

Executive SecretaryMaria Ellis

Wednesday, May 1, 2013, 8:12 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on May 1, 2013, to discuss the evidence, hear presentations and public comment, and make recommendations concerning the use of selected genetic tests for cancer diagnosis for cancers of unknown primary site for cervical cytology findings of uncertain clinical significance.

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

<u>CMS Presentation and Voting Questions.</u> A CMS representative explained some of the definitions that would be used during the discussion and voting, and then read the voting and discussion questions that would be considered by the panel.

<u>Presentations by Invited Guest Speakers.</u> The panel heard presentations from four of the five invited guest speakers. Dr. Whitehead presented the results of the technology assessment performed by RTI International addressing the questions concerning cancer of unknown primary site (CUP). Dr. Conley's presentation focused on current clinical applicability of molecular guided treatment for CUPS. Dr. Uhlig presented the results of the technology assessment performed by Tufts addressing the questions concerning fluorescent in-situ hybridization (FISH) testing. Dr. Rosenthal's presentation focused on clinical applications of FISH testing.

<u>Scheduled Public Comments.</u> The panel heard from a total of six scheduled speakers, including one cancer patient, representatives from professional societies, manufacturer's representatives, and clinicians.

Open Public Comments. The panel heard from one member of the public.

Questions to Presenters. The panel participated in a lengthy discussion and question and answer session with all of the presenters.

<u>Initial Open Panel Discussion</u>, <u>Formal Remarks and Voting Questions</u>. The panel turned its attention to the voting questions, having limited additional discussion before votes on each question. The results of the voting were recorded on electronic devices and recorded manually, announced to the public, and were recorded by CMS staff. Following each voting question, the panelists focused on the discussion questions, comments on which are found in the transcript.

Adjournment. The meeting adjourned at 3:00 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on May 1, 2013, 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.

Rita Redberg, MD, MSc

Chairperson