

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

March 24, 2015

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

Medicare Evidence Development & Coverage Advisory Committee

March 24, 2015

Attendees

Acting Chairperson

I. Craig Henderson, MD

Voting Members

Harry Burke, MD, PhD
Josef E. Fischer, MD
Mark D. Grant, MD, PhD
Beverly A. Guadagnolo, MD, MPH
Mitchell R. Kamrava, MD
Marcel Salive, MD, MPH
Maren T. Scheuner, MD, MPH
Diana Zuckerman, PhD

CMS Liaison

James Rollins, MD

Industry Representative

Lakshman Ramamurthy, PhD

Guest Panel Member

Barry M. Berger, MD, FCAP

Invited Guest Speakers

Barbara Conley, MD
Jeffrey S. Ross, MD

Executive Secretary

Maria Ellis

Tuesday, March 24, 2015, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on March 24, 2015, to discuss the evidence, hear presentations and public comment, and to make recommendations concerning selected molecular pathology tests for the estimation of prognosis in common cancers; adenocarcinoma of the colon and rectum, breast cancer, invasive duct and lobular cancers, non-small cell lung cancers.

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 background information regarding CMS's consideration of evidence thus far, and then read the voting and discussion questions that would be considered by the panel.

TA Presentation. Dr. Meleth presented the results of a technology assessment conducted by the RTI-UNC Evidence-Based Practice Center looking at the tests for the estimation of prognosis of common cancers.

Presentations by Invited Guest Speakers. The panel heard presentations from the two invited guest speakers. Dr. Conley discussed the clinical validity and clinical utility, as well as the analytical validity of the tests being discussed. Dr. Ross gave the panel an overview of the evolution of molecular pathology and discussed the state of the art tests currently being used.

Scheduled Public Comments. The panel heard from three scheduled speakers, including a molecular pathologist representing the College of American Pathologists, the vice president of clinical affairs of Agendia, and the head of medical affairs for Abbott Medical. It was noted that one of the scheduled speakers was unable to appear to make his presentation, but that it had been received and reviewed by the panel.

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

Initial Open Panel Discussion, Formal Remarks and Voting Questions. The panel turned its attention to the voting questions, conducting a discussion among the panelists before voting. During this discussion, a consensus was reached among the panel to change the wording of questions 1(a) and 1(b), deleting the word "prognostic" and substituting the words "molecular pathology" in the opening of each question, and to change the wording of question 2, inserting the phrase "a change in management that might lead to" between the words "including" and "benefits". The results of the voting were recorded on electronic devices, recorded manually, announced to the public, and were recorded by CMS staff. Following the voting questions the panelists focused on the discussion question, comments on which are found in the transcript.

Adjournment. The meeting adjourned at 3:10 p.m.

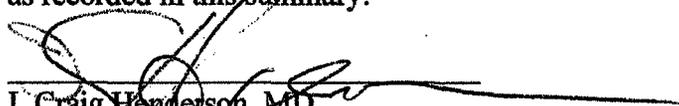
I certify that I attended the meeting
of the Medicare Evidence Development
& Coverage Advisory Committee on
March 24, 2015, and that these minutes
accurately reflect what transpired.



Maria A. Ellis

Executive Secretary, MEDCAC, CMS

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



I. Craig Henderson, MD
Acting Chairperson