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

April 27, 2016

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

Medicare Evidence Development & Coverage Advisory Committee

April 27, 2016

Attendees

Committee Acting Chairperson
Peter Bach, MD, MAPP

Committee Acting Vice Chairperson
Aloysius B. Cuyjet, MD, MPH

Voting Members
Harry Burke, MD, PhD
Salvador Cruz-Flores, MD, MPH
Roger J. Lewis, MD, PhD, FACEP
Gail Melkus, EdD, C-NP, FAAN
Daniel A. Ollendorf, PhD
Thaddeus M. Pope, JD, PhD
Marcel Salive, MD, MPH
Guofen (Evelyn) Yan, PhD

Industry Representative
Theodore C. Lystig, PhD

Guest Panel Members
William T. Carpenter, Jr., MD
Bradley Gaynes, MD, MPH
Carlos A. Zarate, Jr., MD

Invited Guest Speakers
Madhukar Trivedi, MD
Matthew Rudorfer, MD

CMS Liaison
Tamara Syrek Jensen, JD

Executive Secretary
Maria Ellis

Wednesday, April 27, 2016, 8:21 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on April 27, 2016, to discuss the evidence, hear presentations and public comment, to discuss the recommendations regarding the definition of treatment resistant depression (TRD), and to provide advice to CMS on the use of the definition of TRD in the context of coverage with evidence development and treatment outcomes.

The meeting began with a reading of a conflict of interest statement and welcoming remarks.

CMS Presentation and Voting Questions. A CMS representative presented information regarding definitions of terms applicable for the meeting and the panel's consideration of the questions, and then read the voting and discussion questions that would be considered by the panel.

Introduction of Panel. Each member of the panel introduced themselves and stated whether they had any conflicts of interest.

Presentations by Invited Guest Speakers. The panel heard presentations from the two invited guest speakers. Dr. Trivedi stated that there is no universally accepted definition of TRD and that attempts to define it by counting the number of failed adequate treatments was not useful. He discussed the size of problems surrounding treatment resistant depression, impacts to society, and presented the ways different researchers have tried to arrive at a useful definition for TRD. Dr. Rudorfer addressed classic research designs for depression treatments, sham treatments of control groups in device trials, the placebo response, using a stepwise sequence of medications, the importance of the consideration of comorbid conditions, and practice guidelines for non-response to medication. He also discussed depression rating scores versus use of somatic symptoms in defining response to treatment.

Scheduled Public Comments. The panel heard from a total of eight scheduled speakers, including researchers, practitioners, patients who've suffered from TRD, and an industry representative. The researchers informed the committee of current and planned trials related to TRD and summarized some of their clinical experiences. The patients related their experiences with TRD, focusing on finding an effective treatment. The industry representative addressed question four and summarized several trials for FDA approved drugs and interventions.

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 next-to-last bullet on question two to suicidal ideation, to change the last bullet on question two to suicide attempts, and to change question 4.f to time to relapse. 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 on question four the panelists addressed its discussion question, comments on which are found in the transcript.

Adjournment. The meeting adjourned at 3:37 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on April 27, 2016, 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.

Peter Bach, MD, MAPP
Acting Chair