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

**August 22, 2018**

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

# Medicare Evidence Development & Coverage Advisory Committee

## August 22, 2018

## Attendees

**Acting Committee Chair**
Joseph Ross, MD, MHS

**Committee Vice-Chair**
Aloysius B. Cuyjet, MD, MPH

**MEDCAC Members**
Joseph S. Cheng, MD, MS, FACS, FAANS
Diane Civic, PhD, MPH, MSW
Naftali Zvi Frankel, MS
Melissa M. Garrido, PhD, BS
Thomas F. Goss, PharmD
Thomas James III, MD, FACP, FAAP
Joel Lamon, MD, FACP
Carla Perissinotto, MD, MPH

**Industry Representative**
Shamiram Feinglass, MD, MBA

**Guest Panel Members**
Stephen Gottschalk, MD
Doug Olson, MD
James C. Yang, MD

**Invited Guest Speakers**
Elissa Bantug, MHS
Ethan Basch, MD
Ilia Ferrussi, PhD
William Go, MD, PhD
Paul Kluetz, MD
Claire Snyder, PhD

**CMS Liaison**
Tamara Syrek Jensen, JD

**Executive Secretary**
Maria Ellis

**Wednesday, August 25, 2018, 8:10 a.m.**

The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) met on August 22, 2018, to discuss their appraisal and recommendations regarding the state of the evidence on CAR T-cell therapy, related to the collection of patient-reported outcomes (PROs) in cancer clinical studies.

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

**CMS Presentation.** A CMS representative informed the panel and audience that this meeting was being held as part of the CMS review of a formal request for a national coverage determination for chimeric antigen receptor (CAR) T-cell therapy, and that the meeting is being held specifically to receive MEDCAC recommendations regarding how existing PRO assessment tools should be incorporated into future clinical studies on CAR T-cell therapy, clinical study design characteristics, study duration, and suitable study controls. She then read the voting and discussion questions to be acted upon by the panel, explaining the terms used therein.

**Presentations by Invited Guest Speakers.** The panel heard presentations from the invited guest speakers.

Dr. Go summarized the studies of the specific CAR T-cell therapy YESCARTA, including use of the CIBMTR registry, as well as presenting an overview of evolving CAR T-cell therapy technology. Dr. Go stated Kite Gilead's position that PROs are best served and interpreted in a randomized trial setting and while valuable, they should not be included in coverage decisions at this time.

Dr. Ferrusi shared Novartis' experience with PROs in their clinical studies of Kymria, highlighting the JULIET study. On behalf of Novartis, she urged CMS to use caution in identifying specific PRO measures for future studies of CAR T-cell therapy.

Dr. Kluetz informed the panel of current efforts at the FDA to formulate patient-focused drug development efforts within oncology. His conclusion was that while clinical outcomes complement survival in trials, they do not replace survival, and PROs are a type of clinical outcome.

Dr. Snyder and Ms. Bantug discussed their ongoing research to better display PROs data so that patients and clinicians can better understand the meaning of their scores to better use them in clinical practice and decision making.

Dr. Basch summarized many of the available PRO tools that the panel was assessing. His recommendation for question one was that the PRO-CTCAE, MDASI, EORTC-QLQ-C30 and PROMIS are tools that should be considered, but the evidence is weak related to the UW-QOL, ESRA-C and FLIC. Dr. Basch also opined there are other PRO

assessments that should be considered, highlighting the FACT GP-5 as a companion to the PRO-CTCAE. His conclusion is that PRO provide valuable information, they are shelf ready although work remains to understand what areas should be the outcome of interest.

**Scheduled Public Comments.** The panel heard from a total of six scheduled speakers, including clinicians, researchers and industry representatives. These speakers informed the committee of their views concerning the use of PROs

**Open Public Comments.** One member of the general public, an industry trade organization representative, addressed the panel, urging CMS not to incorporate PROs into any coverage decision for CAR T-cell therapy.

**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 conducted an in depth discussion of the issues raised, before turning its attention to the discussion and voting questions. The votes and discussion points are reflected 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 August 22, 2018, 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.

10/5/18

Joseph Ross, MD, MHS
MEDCAC Acting Committee Chair