

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

(Remote via Zoom)

May 21, 2024

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

Medicare Evidence Development & Coverage Advisory Committee

May 21, 2024

Attendees (Remotely)

Committee Chair

Joseph Ross, MD, MHS

Committee Vice-Chair

Sanket Dhruva, MD, MHS, FACC

MEDCAC Members

Brian Isetts, RPh PhD, BS-Pharm

Alexander Fanaroff, MD, MHS

Melissa M. Garrido, PhD, BS

Fred Kobylarz, MD, MPH

Joy H. Lewis, DO, PhD, FACP

Eric Wall, MD, MPH

Heather Young, PhD, RN, FAAN

Patient Advocate

Naftali Z. Frankel, MS, MBEE

Industry Representative

Mark D. Carlson, MD, MA

CAG Director

Tamara Syrek-Jensen

MEDCAC Coordinator

Tara Hall

Tuesday, May 21, 2024, 10:00 a.m. EST

The Medicare Evidence Development & Coverage Advisory Committee met virtually via Zoom on May 21, 2024, to discuss devices for self-management of type 1 and insulin-dependent type 2 diabetes. The committee met to specifically examine the level of evidence of certain new and innovative technologies. By voting on specific questions and panel discussion, the MEDCAC panel advised CMS about the ideal health outcomes and domains to be addressed in future research studies of devices for diabetes self-management, appropriate measurement instruments, and adequate duration of follow-up, to help provide clarity and transparency in future national coverage decisions.

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

Clinical Endpoints Guidance Program. Dr. Steve Farmer presented an overview of CMS' National Coverage Decision process, highlighting the establishment of a clinical endpoints guidance program to assist manufacturers and other interested parties in understanding the type of evidence CMS expects for review when considering an NCD. He then informed attendees that a CMS contractor had completed a clinical endpoints review of devices for self-management of type 1 and insulin-dependent type 2 diabetes.

CMS Presentation: Clinical Endpoints Review (CER). Teresa Rogstad presented a review of the clinical endpoints review.

Summary of Subcommittee Deliberations, Review of Voting Questions and Discussion Guide. Dr. Ross summarized the February 8, 2024 subcommittee meeting that helped form the questions for this meeting. He then presented the voting questions, explained the voting scale, and outlined the planned agenda.

Scheduled Public Speakers. The panel heard from a total of 13 scheduled speakers, including nine whose remarks were accompanied by Power Point presentations. The speakers included representatives from industry, health policy and research organizations, professional societies, and patient advocacy groups.

Open Panel Discussion. The panel conducted an in-depth discussion, offering opinions and recommendations related to the proposed domains contained in the CER. This discussion can be found in the transcript of the meeting.

Voting Questions. Turning its attention to the voting questions, the panel voted individually on each of the four questions presented. Following the electronic vote each individual panelist, including nonvoting members, announced his or her vote, made comments concerning the vote, and made further suggestions or recommendations for CMS regarding the individual domain or criterion being voted on.

Closing Remarks. Dr. Ross and Dr. Farmer extended thanks to the panelists, presenters, and public for participating in the meeting.

Adjournment. The meeting adjourned at 2:10 p.m. EST, May 21, 2024.

I certify that I attended the meeting
of the Medicare Evidence Development
and Coverage Advisory Committee on
May 21, 2024, and that these minutes
accurately reflect what transpired.

Tara Hall

Tara Hall
MEDCAC Coordinator, CMS

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

Joseph Ross

Joseph Ross, MD, MHS
MEDCAC Chair