

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

February 8, 2024

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

**Medicare Evidence Development & Coverage Advisory Committee
Subcommittee Meeting**

February 8, 2024

Attendees (Remotely)

Committee Chair

Joseph Ross, MD, MHS

Committee Vice-Chair

Sanket Dhruva, MD, MHS, FACC

MEDCAC Members

Fred Kobylarz, MD, MPH
Joy H. Lewis, DO, PhD, FACP

Patient Advocate

Naftali Z. Frankel, MS, MBEE

Industry Representative

Mark D. Carlson, MD, MA

CAG Director

Tamara Syrek-Jensen

MEDCAC Coordinators

Michelle Atkinson
Tara Hall
Leah Cromwell

Thursday, February 8, 2024, 9:53 a.m. EST

The Subcommittee of the Medicare Evidence Development & Coverage Advisory Committee met virtually via Zoom on February 8, 2024, to discuss devices for self-management of type 1 and insulin-dependent type 2 diabetes. The subcommittee met to specifically consider the general requirements for clinical studies submitted for CMS coverage with evidence development (CED), and to recommend voting questions for the upcoming full MEDCAC general requirements for clinical studies submitted for CMS meeting on this topic.

The meeting began with a reading of welcoming remarks from Ms. Cromwell and Dr. Steve Farmer. Chief strategy officer.

CER Review Summary. The subcommittee heard a presentation from Ms. Terry Rogstad, a CMS representative, summarizing the Clinical Endpoints Review conducted under contract to CMS addressing the most commonly clinical endpoints published in studies addressing type 1 or type 2 diabetes.

Questions from Panelists. Following Ms. Rogstad's presentation, she fielded questions from the MEDCAC subcommittee concerning the CER. These questions and related discussion are contained in the transcript of the meeting.

Discussion Questions. The subcommittee had a lengthy discussion around the conclusions and recommendations of the CER. Areas addressed included the appropriateness of the literature search, domains listed, surrogate and nonclinical endpoints, quality of life instruments and minimal clinically important differences. Detailed discussions can be found in the transcript.

Discussion/Refinement of Draft Voting Questions. Following a lunch break, the subcommittee discussed voting questions to be presented to the full MEDCAC. Ms. Rogstad served as a scribe during this discussion, making redline changes to the originally proposed questions reviewed. The final recommendations of the subcommittee can be found in Ms. Rogstad's work product and the transcript of the meeting.

Adjournment. The subcommittee adjourned at 1:58 p.m. EST.

I certify that I attended the meeting
of the Medicare Evidence Development
and Coverage Advisory Committee on
February 8, 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