

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

March 26, 2025

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

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

March 26, 2025

Attendees (Remotely)

Committee Chair

Joseph Ross, MD, MHS

Committee Vice-Chair

Sanket Dhruva, MD, MHS, FACC

MEDCAC Members

Pooja Khatri, Kobylarz, MD

Timothy Barreiro, DO

Patient Advocate

Amy Goldsmith, MA, CCC-SLP, RAC-CT, CMAC

Industry Representative

Laura Mauri, MD, MSc

MEDCAC Coordinator

Tara Hall

Wednesday, March 26, 2025, 10:00 a.m. EST

The Subcommittee of the Medicare Evidence Development & Coverage Advisory Committee met virtually via Zoom on March 26, 2025, to discuss devices to manage tremor in Parkinson's disease and essential tremor. The subcommittee met to specifically consider the most important endpoints and appropriate duration in clinical studies submitted for CMS coverage with evidence development (CED), and to recommend voting questions for the upcoming full MEDCAC.

The meeting began with a reading of welcoming remarks from Ms. Hall and Dr. Steve Farmer, chief strategy officer.

CER Review Summary. The subcommittee heard a presentation from Ms. Terry Rogstad, Senior Advisor, summarizing the Clinical Endpoints Review conducted under contract to CMS addressing the most commonly clinical endpoints that are used in studies of devices for the management of tremor in Parkinson's disease, and essential tremor.

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, whether appropriate and most important clinical endpoints are adequately identified, differing endpoints between patient subpopulations and device, types of measurement instruments used and significance of minimal clinically important differences (MCIDs), and domain specific minimum duration of follow-ups within trials. Detailed discussions can be found in the transcript.

Discussion/Refinement of Draft Voting Questions. Following a short break, the subcommittee discussed voting questions to be presented to the full MEDCAC. Point of consensus among the subcommittee was that rather than voting on separate devices, the committee should vote on domains, then pointing out in a comment the most significant devices. The final recommendations of the subcommittee can be found in the transcript of the meeting.

Adjournment. The subcommittee adjourned at 12:21 p.m. EDT.

I certify that I attended the meeting
of the Medicare Evidence Development
and Coverage Advisory Committee on
March 26, 2025, 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