

Medicare Evidence Development & Coverage
Advisory Committee

September 12, 2007

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

September 12, 2007

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

Medicare Evidence Development & Coverage
Advisory Committee

September 12, 2007

Medicare Evidence Development and Coverage Advisory Committee (MedCAC)

September 12, 2007

Attendees

Vice-Chair

Steven Pearson, M.D., M.Sc.

Voting Members

- Gregory L. Barkley, M.D.
- Karl E. Becker, M.D., M.B.A.
- Mark V. Boswell, M.D., Ph.D.
- Gregory J. Dehmer, M.D.
- Marion Danis, M.D.
- Saty Satya-Murti, M.D., F.A.N.N.
- Mercedes K.C. Dullum, M.D.
- Loren Hiratzka, M.D.
- Marvin Konstam, M.D.

CMS Liaison

Louis Jacques, M.D.

Consumer Representative

Randel Richner, B.S.N., M.P.H.

Industry Representative

Peter Juhn, M.D., M.P.H.

Guest Expert Panelists

- Doran Edwards, M.D.
- Barry L. Whites, M.D., F.C.C.P.

Executive Secretaries

- Maria Ellis
- Michelle Atkinson

Medicare Evidence Development & Coverage
Advisory Committee

3

September 12, 2007

Wednesday, September 12, 2007, 8:05 a.m.

The MedCAC met on September 12, 2007, to discuss the evidence, hear presentations and public comment, and make recommendations regarding the diagnosis and treatment of obstructive sleep apnea (OSA) in Medicare beneficiaries who may be candidates for continuous positive airway pressure (CPAP) therapy, and alternatives to facility-based polysomnography in the diagnosis of OSA, including home sleep testing devices and clinical diagnosis without the use of sleep testing.

The meeting began with a reading of conflict of interest issues, opening remarks by the vice chair and CMS liaison, and introduction of the Committee.

CMS Summary and Presentation of Voting Questions. A CMS representative presented the discussion and voting questions to be considered by the panel.

Presentation on behalf of Requestor. The panel heard from a representative of the American Academy of Otolaryngology - Head and Neck Surgery supporting broadening the application and use of in-home sleep monitoring.

Presentation of the Technology Assessment. The results of a technology assessment performed by the Tufts New England Medical Center Evidence-Based Practice Center were presented.

Other Presentations. The panel heard presentations from a member of the CMS staff, and a Canadian researcher.

Scheduled Public Comments. Fifteen speakers, including professional society representatives, manufacturers' representatives, clinicians and other healthcare professionals, addressed the panel.

Medicare Evidence Development & Coverage
Advisory Committee

September 12, 2007

Open Public Comments. Following the scheduled public comments, the panel heard

from four additional speakers.

Questions to Presenters. The panel conducted an extensive question and answer period with the various presenters and other speakers.

Initial Open Panel Discussion. There was an extensive period of discussion surrounding the initial discussion questions, as well as the form of the voting questions and definitions to be applied during the deliberations and voting.

Formal Remarks and Voting. The panel voted on the following questions:

One. How confident are you that there is sufficient evidence to determine that each of the following strategies can in routine use produce an accurate diagnosis of OSA for the prescription of CPAP?

Two. For each OSA diagnostic strategy for which there is enough evidence in question one, how confident are you about the sensitivity, ability to minimize false negatives, and specificity, ability to minimize false positives?

Three. Should each of the following be weighed as a criterion for the prescription of CPAP for the diagnosis of OSA?

Four. CPAP is currently a standard treatment for OSA. Defining successful treatment as combined subjective improvement of OSA clinical signs or symptoms and continued patient use of CPAP for two or more months, how confident are you that there is sufficient evidence to determine the ability of each of the following diagnostic strategies to accurately predict successful treatment of OSA with CPAP?

Five. How confident are you that each of the following diagnostic strategies will accurately predict successful treatment of OSA with CPAP?

Medicare Evidence Development & Coverage
Advisory Committee

September 12, 2007

Six. How confident are you that no clinically meaningful harm to patients will be caused by a trial by CPAP strategy as an alternative to strategies that require a positive prior PSG or home sleep test before CPAP?

Seven. How confident are you that your conclusions can be generalized to, A, the Medicare population, and B, providers in community practice?

The results of the voting were recorded on individual tally sheets and compiled by staff. During the voting procedure, further discussion was held among the panelists concerning each question voted upon, and individual comments were made by panelists during each vote, amplifying their reasons for voting as they did.

September 12, 2007

Medicare Evidence Development & Coverage
Advisory Committee

Adjournment. The meeting adjourned at 3:00 p.m.

I certify that I attended the meeting
of the MedCAC Committee on
September 12, 2007, and that these minutes
accurately reflect what transpired.

Maria Ellis
Executive Secretary, MedCAC, CMS

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

Steven Pearson, M.D., M.Sc.
Vice Chair