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

September 28, 2004

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland
Medicare Coverage Advisory Committee

September 28, 2004

Attendees

Ronald M. Davis, M.D.
Chairperson

Barbara J. McNeil, M.D., Ph.D.
Vice-Chairperson

Janet Anderson Brock
Executive Secretary

Voting Members
David C. Dale, M.D.
G. Scott Gazelle, M.D., M.P.H., Ph.D.

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Clifford Goodman, Ph.D.
Alexander Krist, M.D.
Michael Maves, M.D., M.B.A.
Rita F. Redberg, M.D., M.Sc., FACC
Jonathan P. Weiner, Ph.D.

CMS Liaison
Steve Phurrough, M.D., M.P.A..

Consumer Representative
Joan I. Samuelson

Industry Representative
Michael Lacey, M.Sc.

Guest Panelists
Robert D. Hoover, M.D., M.P.H.
S. Satya-Murti, M.D.
Barry Whites, M.D., FCCP, MSHA

Tuesday, September 28, 2004, 8:05 a.m.
The Medicare Coverage Advisory Committee met on September 28, 2004, to discuss and make recommendations concerning the quality of the evidence and related issues for the use of portable multichannel home sleep testing as an alternative to facility based polysomnography.

The meeting began with a reading of the conflict of interest statement and introduction of the Committee.

CMS Presentation of Request and Voting/Discussion Questions. Dr. Sanders, a CMS representative, presented the panel with background information on obstructive sleep apnea (OSA), noting FDA approval for certain devices. She also informed the panel that current CMS coverage extends only to continuous positive airway pressure (CPAP) for moderate to severe OSA, where surgery is a likely alternative, and when a facility based polysomnography, not in home or mobile, had been performed. She then presented the questions that the panel would be asked to vote upon at the conclusion of this meeting.

AHRQ Presentation of Technology Assessment. Dr. Brian Boehleche presented a summary of the evidence review conducted by Research Triangle Institute. Following his presentation, the panel was given the opportunity to ask specific questions concerning the review.

Requestor's Presentation and Scheduled Public Comments. Dr. Terence Davidson, the requestor, presented the panel with information supporting the request for coverage. Following his presentation, the panel heard from thirteen other scheduled speakers, including representatives of the American Academy of Sleep Medicine, American Thoracic Society, American Academy of Otolaryngology and the American Sleep Apnea Association. Other scheduled speakers included private practitioners, researchers and representatives of sleep laboratories and manufacturers. The panel posed questions to several of the scheduled speakers.

Open Public Comments. Seven speakers addressed the panel, including a representative from the American College of Chest Physicians, five practicing physicians, and a representative of a manufacturer of portable devices.

Open Panel Discussion. Following a lunch break, the panel engaged in a general discussion, including extensive questioning of many of the presenters.

Final Remarks and Vote. During their final remarks, the consensus of the panel was to change the wording of Question 4b for both parameters, as indicated in the transcript and this summary. The panel voted on the following questions:

FOR CARDIORESPIRATORY MEASURES ONLY:

Question 1. How well does the evidence address the effectiveness of this type of unattended portable multichannel home sleep testing devices as an alternative to facility

based polysomnography in the diagnosis of obstructive sleep apnea, or OSA? One voting member indicated poorly (level 1); three voting members and two nonvoting panelists indicated poor to reasonably well (level 2); and four voting members and three nonvoting panelists indicated reasonably well (level 3).

Question 2. How confident are you in the validity of the scientific data for the following outcomes:

a. Acquisition of interpretable data? Four voting members and two nonvoting panelists indicated no to moderate confidence (level 2), and four voting members and three nonvoting panelists indicated a moderate confidence (level 3).
b. Ability to accurately diagnose OSA (sensitivity)? One voting member indicated little to no confidence (level 1.5); one nonvoting panelist indicated no to moderate confidence (level 2); seven voting members and two nonvoting panelists indicated moderate confidence (level 3); and two nonvoting panelists indicated moderate to high confidence (level 4).
c. Ability to accurately identify those without OSA (specificity)? One voting member indicated little to no confidence (level 1.5); seven voting members and four nonvoting panelists indicated moderate confidence (level 3); and one nonvoting panelist indicated moderate to high confidence (level 4).

Question 3. How likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnography for the following outcomes?

a. Acquisition of interpretable data? One voting member indicated not likely (level 1); five voting members and two nonvoting panelists indicated not to reasonably likely (level 2); one voting member and one nonvoting panelist indicated reasonably likely (level 3); and one voting member and two nonvoting panelists indicated very likely (level 5).
b. Ability to accurately diagnose OSA (sensitivity)? Two voting members and one nonvoting panelist indicated not to reasonably likely (level 2); six voting members and two nonvoting panelists indicated reasonably likely (level 3); one nonvoting panelist indicated reasonably to very likely (level 4); and one nonvoting panelist indicated very likely (level 5).
c. Ability to accurately identify those without OSA (specificity)? Three voting members and two nonvoting panelists indicated not to reasonably likely (level 2); four voting members and one nonvoting panelist indicated reasonably likely (level 3); and one voting member and two nonvoting panelists indicated reasonably to very likely (level 4).

Question 4a. How confident are you that these sleep testing devices are as accurate in the diagnosis of obstructive sleep apnea as is a facility based test? Five voting members and two nonvoting panelists indicated no to moderate confidence (level 2); two voting members and one nonvoting panelist indicated moderate confidence (level 3); one voting member and one nonvoting panelist indicated moderate to high confidence (level 4); and one nonvoting panelist indicated high confidence (level 5).

Question 4b. How confident are you that use of these sleep testing devices in the diagnosis of obstructive sleep apnea will lead to similar or improved health outcomes measured either directly or indirectly through changes in patient management as compared to a facility based test? Two voting members and two nonvoting panelists indicated no to moderate confidence (level 2); three voting members and one nonvoting panelist indicated moderate confidence (level 3); three voting members and one nonvoting panelist indicate moderate to high confidence (level 4); and one nonvoting panelist indicated high confidence (level 5).

Question 4c. How confident are you that these sleep testing devices are as accessible as is a facility based test for the diagnosis of obstructive sleep apnea? Six voting members and two nonvoting panelists indicated moderate to high confidence (level 4), and two voting members and three nonvoting panelists indicated high confidence (level 5).

Question 5. Based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to:

a. The Medicare population (aged 65+)? One voting member and three nonvoting panelists indicated not likely (level 1); five voting members indicated not to reasonably likely (level 2); two voting members indicated reasonably likely (level 3); and two nonvoting panelists indicated reasonably to very likely (level 4).

b. Providers (facilities/physicians) in community practice? Four voting members and three nonvoting panelists indicated not to reasonably likely (level 2); four voting member indicated reasonably likely (level 3); one nonvoting panelist indicated reasonably to very likely (level 4); and one nonvoting panelist indicated very likely (level 5).

SLEEP AND RESPIRATORY PARAMETERS

Question 1. How well does the evidence address the effectiveness of this type of unattended portable multichannel home sleep testing devices as an alternative to facility based polysomnography in the diagnosis of obstructive sleep apnea, or OSA? Three voting members indicated poorly (level 1); three voting members and two nonvoting panelists indicated poor to reasonably well (level 2); one voting member and two nonvoting panelists indicated reasonably well (level 3); and one voting member and one nonvoting panelist indicated reasonably to very well (level 4).

Question 2. How confident are you in the validity of the scientific data for the following outcomes:

a. Acquisition of interpretable data? Six voting members and three nonvoting panelists indicated no to moderate confidence (level 2); one voting member and two nonvoting panelists indicated moderate confidence (level 3); and one voting member indicated moderate to high confidence (level 4).

b. Ability to accurately diagnose OSA (sensitivity)? Six voting members and one nonvoting panelist indicated no to moderate confidence (level 2); two voting members and three nonvoting panelists indicated moderate confidence (level 3); and one nonvoting panelist indicated moderate to high confidence (level 4).

c. Ability to accurately identify those without OSA (specificity)? Three voting members and one nonvoting panelist indicated no to moderate confidence (level 2); and five voting members and four nonvoting panelists indicated moderate confidence (level 3).

Question 3. How likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnography for the following outcomes?

a. Acquisition of interpretable data? One voting member indicated not likely (level 1); six voting members and two nonvoting panelists indicated not to reasonably likely (level 2); one voting member and two nonvoting panelists indicated reasonably likely (level 3); and one nonvoting panelist indicated very likely (level 5).

b. Ability to accurately diagnose OSA (sensitivity)? Two voting members and two nonvoting panelists indicated not to reasonably likely (level 2); six voting members and one nonvoting panelist indicated reasonably likely (level 3); one nonvoting panelist indicated reasonably to very likely (level 4); and one nonvoting panelist indicated very likely (level 5).

c. Ability to accurately identify those without OSA (specificity)? One voting member and one nonvoting panelist indicated not to reasonably likely (level 2); six voting members and two nonvoting panelists indicated reasonably likely (level 3); and one voting member and two nonvoting panelists indicated reasonably to very likely (level 4).

Question 4a. How confident are you that these sleep testing devices are as accurate in the diagnosis of obstructive sleep apnea as is a facility based test? Five voting members and one nonvoting panelist indicated no to moderate confidence (level 2); two voting members and three nonvoting panelists indicated moderate confidence (level 3); and one voting member and one nonvoting panelist indicated moderate to high confidence (level 4).

Question 4b. How confident are you that use of these sleep testing devices in the diagnosis of obstructive sleep apnea will lead to similar or improved health outcomes measured either directly or indirectly through changes in patient management as compared to a facility based test? Three voting members and two nonvoting panelists indicated no to moderate confidence (level 2); three voting members and one nonvoting panelist indicated moderate confidence (level 3); two voting members and one nonvoting panelist indicated moderate to high confidence (level 4); and one nonvoting panelist indicated high confidence (level 5).

Question 4c. How confident are you that these sleep testing devices are as accessible as is a facility based test for the diagnosis of obstructive sleep apnea? Six voting members and four nonvoting panelists indicated moderate to high confidence (level 4), and two voting members and one nonvoting panelist indicated high confidence (level 5).

Question 5. Based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to:

a. The Medicare population (aged 65+)? One voting member and one nonvoting panelist indicated not likely (level 1); six voting members and two nonvoting panelists indicated not to reasonably likely (level 2); one voting member and one nonvoting panelist indicated reasonably likely (level 3); and one nonvoting panelist indicated reasonably to very likely (level 4).

b. Providers (facilities/physicians) in community practice? One voting member indicated not likely (level 1); three voting members and four nonvoting panelists indicated not to reasonably likely (level 2); four voting member indicated reasonably likely (level 3); and one nonvoting panelist indicated very likely (level 5).

Adjournment. The meeting adjourned at 4:15 p.m.

I certify that I attended the meeting of the Executive Committee on September 28, 2004, and that these minutes accurately reflect what transpired.

Janet Anderson Brock
Executive Secretary, MCAC, CMS

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

Ronald M. Davis, M.D.
Chairperson