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

November 4, 2004

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland

Medicare Coverage Advisory Committee

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Attendees

Ronald M. Davis, M.D.
Chairperson

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

Kimberly Long
Executive Secretary

Voting Members
David J. Margolis, M.D., Ph.D.
Clifford Goodman, Ph.D.
Brent J. O'Connell, M.D.
Jonathan P. Weiner, Ph.D.
Jed Weissberg, M.D.
Michael Abecassis, M.D.
Kieren P. Knapp, D.O.
William F. Owen, Jr., M.D.

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

Industry Representative
G. Gregory Raab, Ph.D.

Guest Panelists
Sam Klein, M.D., M.S.
Henry Buchwald, M.D., Ph.D.
Harvey Sugerman, M.D.

Thursday, November 4, 2004, 8:06 a.m.

The Medicare Coverage Advisory Committee met on November 4, 2004, to discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of bariatric surgery for the treatment of morbid obesity.

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

CMS Summary of Evidence and Presentation of Voting Questions. A CMS representative presented the panel with information on Medicare coverage, the epidemiology of obesity, and the current mechanisms and types of bariatric surgery, followed by their procedure for evidence review and their results and conclusions. He then presented the questions that the panel would be asked to vote upon at the conclusion of this meeting. Following the presentation, the committee was given the opportunity to ask questions of the representative.

Scheduled Public Comments. A group of seven individuals addressed the panel concerning their opinions on the need to review current CMS policy regarding coverage for bariatric surgery in the treatment of morbid obesity. These speakers included bariatric surgeons and representatives of related professional associations including the American Society for Bariatric Surgery and the North American Association for the Study of Obesity, a representative of Kaiser Permanente, as well as two patients who had undergone bariatric surgery for treatment of morbid obesity. Following the group presentation, the panel heard from fifteen other scheduled speakers, including representatives of the American Dietetic Association and the American College of

Surgeons. Other scheduled speakers included private practitioners and researchers, a medical director of a nutrition and weight management center, and three more patients who had undergone bariatric surgery. The panel posed questions to several of the scheduled speakers after the presentations.

Open Public Comments. Six speakers addressed the panel, including a representative from an obesity support group, an anesthesiologist who serves as the medical director of a manufacturer for bariatric surgical supplies, another manufacturer's representative, and two surgeons and researchers.

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.

I. OBESITY PATIENTS WITH ONE OR MORE COMORBIDITIES:

Question 1. How well does the evidence address the effectiveness of bariatric surgery in the treatment of obesity in patients with one or more comorbidities compared with nonsurgical medical management? Four voting members indicated reasonably to very well (level 4); five voting members and all four nonvoting panelists indicated very well (level 5).

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

Weight loss (sustained)? Four voting members indicated moderate to high confidence (level 4); five voting members and all four nonvoting panelists indicated high confidence (level 5).

Long-term survival? Three voting members indicated moderate confidence (level 3); six voting members and one nonvoting panelist indicated moderate to high confidence (level 4); and three nonvoting panelists indicated high confidence (level 5).

Short-term mortality? Three voting member indicated moderate confidence (level 3); five voting members indicated moderate to high confidence (level 4); and one voting member and all four nonvoting panelists indicated high confidence (level 5).

Comorbidities? One voting member indicated moderate confidence (level 3); six voting members indicated moderate to high confidence (level 4); and two voting members and all four nonvoting panelists indicated high confidence (level 5).

Question 3. How likely is it that bariatric surgery, including RYGBP, banding, and BPD, will positively affect the following outcomes in obese patients with one or more comorbidities compared to nonsurgical medical management?

Weight loss (Sustained)? One voting member indicated reasonably to very likely (level 4); eight voting members and all four nonvoting panelists indicated very likely (level 5).

Long-term survival? Three voting members indicated reasonably likely (level 3); five voting members and one nonvoting panelist indicated reasonably to very likely (level 4); and one voting member and three nonvoting panelists indicated very likely (level 5).

Short-term mortality? Four voting members indicated reasonably likely (level 3); four voting members and one nonvoting panelist indicated reasonably to very likely (level 4); and one voting member and three nonvoting panelists indicated very likely (level 5).

Comorbidities? One voting member indicated reasonable likely (level 3): two voting members indicated reasonably to very likely (level 4): and six voting members and all four nonvoting panelists indicated very likely (level 5).

Question 4. How confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients with one or comorbidities?

RYGBP – open: Seven voting members and one nonvoting panelist indicated moderate to high confidence (level 4); two voting members and three nonvoting panelists indicated high confidence (level 5).

RYGBP – laparoscopic (lap): Four voting members indicated moderate to high confidence (level 4); five voting members and all four nonvoting panelists indicated high confidence (level 5).

BPD – open: Three voting members indicated moderate confidence (level 3); six voting members and one nonvoting panelist indicated moderate to high confidence (level 4); and three nonvoting panelists indicated high confidence (level 5).

BPD – lap: One voting member indicated moderate confidence (level 3); six voting members indicated moderate to high confidence (level 4); and two voting members and all four nonvoting panelists indicated high confidence (level 5).

Banding – open: One voting member indicated no to moderate confidence (level 2): four voting members indicated moderate confidence (level 3); four voting members and one nonvoting panelist indicated moderate to high confidence (level 5); and three nonvoting panelists indicated high confidence (level 5).

Adjournment. The meeting adjourned at 3:45 p.m.

I certify that I attended the meeting of the Executive Committee on November 4, 2004, and that these minutes accurately reflect what transpired.

Kimberly Long

Kimberly Long
Executive Secretary, MCAC, CMS

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

Ronald M. Davis, M.D.
Chairperson