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

March 29, 2005

Centers for Medicare and Medicaid Services
7500 Security Boulevard
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
Edgar R. Black, M.D.
David J. Margolis, M.D., Ph.D.
Catherine A. Glennon, R.N.
Angus M. McBryde, Jr., M.D.
Harry B. Burke, M.D., Ph.D.
Steven N. Goodman, M.D., M.H.S., Ph.D.
Jonathan P. Weiner, Ph.D.

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

Consumer Representative
Charles J. Queenan, III

Industry Representative
Kim K. Kuebler, M.N., R.N.

Guest Panelists
Harod Brem, M.D.
Susan D. Horn, Ph.D.
William B. Greenough, III, M.D.
Elizabeth A. Ayello, Ph.D., R.N.

Wednesday, March 29, 2005, 8:06 a.m.

The Medicare Coverage Advisory Committee met on March 29, 2005, to discuss the evidence, hear presentations and public comment, and make recommendations regarding usual care of chronic wounds.

The meeting began with an introduction of the Committee.

CMS Summary and Presentation of Voting Questions. A CMS representative presented the panel with a general overview of chronic wounds and their impact on the U.S. population, CMS's coverage position on chronic wound therapy, problems encountered in the literature evaluating treatment for chronic wounds, and goals, as well as questions for the MCAC committee.

Presentation of the Technology Assessment. Dr. Tom O'Donnell presented a summary of the technology assessment performed at the Tufts/New England Medical Center.

Presentation by Panelists. Dr. Horn, Dr. Ayello, and Dr. Margolis made presentations to the panel regarding the current usual care and treatment for pressure ulcers, diabetic foot ulcers, and venous leg ulcers, respectively. Other panelists were given the opportunity to ask questions.

Scheduled Public Comments. Eighteen speakers addressed the panel concerning the topic of usual care for chronic wounds. These speakers included seven representatives of the Alliance of Wound Care Stakeholders, three representatives of the Wound Healing Cooperative Group, a podiatrist in private practice, representatives of four professional associations, and three representatives of manufacturers of products utilized in the care and treatment of chronic wounds.

Questions to Presenters. The panel was given the opportunity to pose questions to the presenters, including those presenters from the panel.

Open Public Comments. Four additional speakers addressed the panel, including a medical director, a consultant to manufacturers, and two wound care nurses.

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.

The consensus of the panel is indicated following each question.

QUESTION 1: Usual care for chronic wounds commonly includes debridement, cleansing, dressing, compression, antibiotics and off-loading.

a. Is there sufficient evidence to assess the health benefit of these modalities?

b. Are there other modalities that provide a health benefit?

The panel felt that this question is better answered in the response to Question 4.

QUESTION 2: The panel amended Question 2 as follows, with the panel's consensus relating to specific outcomes indicated in parentheses:

The following outcomes are commonly used to assess healing of chronic wounds:

Time to complete healing (Yes);

Partial healing rate, depending on scale-change over time (Yes);

Recurrence rate (No);

Elimination of infection (No);

Amputation rate (Yes);

Validated quality of life measures (Yes);

Percent healed (Yes).

Based on these amendments, the panel felt that Questions 2.a, 2.b and 2.c would be answered consistent with their feeling on the different outcome measures.

QUESTION 3. Based on evidence reviewed, how likely is it that the treatments discussed in Question 1 will positively affect the outcomes discussed in Question 2? The panel deferred answering this question directly, with a consensus agreeing their response to Question 4 would apply to this question as well.

QUESTION 4. Based on the evidence reviewed, do the treatments reviewed in Question 1, singly or in combination, produce clinically significant net health benefits in the treatment of chronic wounds? (Yes)

QUESTION 5. Based on the evidence reviewed, how likely is it that usual care used to treat chronic wounds can be generalized to:

a. The Medicare population (aged 65+). (Yes, likely)

b. Providers (Facilities/physicians) in community practice. (Not sufficient evidence.)

QUESTION 6. What are the knowledge gaps in current evidence pertaining to the usual care of chronic wounds? (Training of staff, education level of staff, patient education, wound product knowledge.)

QUESTION 7. What trial designs will support the development of sufficient evidence to determine the appropriate treatment of chronic wounds? (Large prospective representative trials, RCTs – don't have to control for covariates. Begin studies with various intensities.)

What units of analysis and covariates can be considered? (Large comparative databases to determine what treatment combinations are effective.)

Remarks. During the discussion and votes, each voting member and nonvoting panelist was given the opportunity to make a statement summarizing reasons for their opinions.

Adjournment. The meeting adjourned at 4:05 p.m.

I certify that I attended the meeting of the Medicare Coverage Advisory Committee on March 29, 2005, 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

Ronald M. Davis, M.D.
Chairperson