

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

November 18, 2009

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

Medicare Evidence Development & Coverage Advisory Committee

November 18, 2009

Attendees

Clifford Goodman, Ph.D.
Chairperson

Saty Satya-Murti, M.D., F.A.A.N.
Vice-Chairperson

Maria A. Ellis
Executive Secretary

Voting Members

Catherine Eng, M.D., F.A.C.P.
John Cox, D.O., F.A.C.P.
Philip B. Gorelick, M.D., M.P.H.
Josef E. Fischer, M.D.
Nora A. Janjan, M.D., M.P.S.A.
Norman S. Kato, M.D., M.P.S.A.
Stephen Pauker, M.D., M.A.C.P., F.A.C.C.
Gurkirpal Singh, M.D.
Craig Umscheid, M.D., M.S.C.E.

CMS Liaison

Tamara Syrek Jensen, J.D.

Industry Representative

Kim K. Kuebler, M.N., A.P.R.N.-B.C.

Patient Advocate

Susan Kendig, J.D., M.S.N.

Guest Panel Members

Janice Cormier, M.D.
Naomi Lynn Hurwitz Gerber, M.D.
Lucinda A. Pfalzer, P.T., Ph.D.

Guest Speakers

Jane M. Armer, Ph.D., R.N., F.A.A.N.
Stanley G. Rockson, M.D.

Wednesday, November 18, 2009, 8:08 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on November 18, 2009, to discuss the evidence, hear presentations and public comment, and make recommendations regarding the diagnosis and treatment of secondary lymphedema.

The meeting began with a reading of a conflict of interest statement, welcoming remarks, and an introduction of the Committee.

CMS Presentation and Voting Questions. A CMS representative presented the panel and audience with the agenda for the meeting and the questions that would be considered and discussed or voted on by the panel. The lead medical officer for this panel made a presentation including the definition of lymphedema and current methods of diagnosis and treatment.

Presentation of Technology Assessment. The results of the technology assessment conducted by the McMaster University Evidence-based Practice Centre were presented. Following the presentation, the panel asked questions of the presenters concerning the assessment.

Presentation by Guest Speakers. The panel heard presentations from Dr. Rockson and Dr. Armer. Following Dr. Rockson's presentation, because he had a travel commitment, the panel asked questions concerning the specific topics addressed. Questions for Dr. Armer were deferred until the general questions to presenters section of the agenda.

Scheduled Public Comments. The panel heard from a total of 13 scheduled speakers, including clinicians and researchers, other practitioners, and industry and professional society representatives.

Open Public Comments. The panel heard from seven members of the public, including clinicians and researchers, and device manufacturers.

Questions to Presenters. There was an extensive questioning period where the panel was given the opportunity to pose questions to the presenters.

Initial Open Panel Discussion. The panel conducted an extensive discussion on each of the questions posed by CMS. This discussion included input from the chair, members of the panel, and presenters as requested by members of the panel. During this discussion it was initially agreed by the panel to not consider the phrase "including subclinical disease" in questions one and two, although that changed for certain subcategories prior to the final votes. The panel also agreed to insert social integration under question 4.ix, instead of other. The panel also agreed to add complex decongestive therapy under questions 5.vi and 6.vi, instead of other.

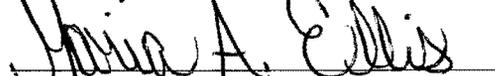
Formal Remarks and Voting Questions. The panel turned its attention to the voting questions, having some additional comments before votes on each question. The results

of the voting were shown to the public on cards and recorded by staff. Prior to concluding votes on question one, the panel decided to vote regarding subclinical disease only as to perometry, bioimpedance and patient recorded symptomatology. The panel added questions 5.vii and 6.vii, to include an evaluation of complex decongestive therapy plus pneumatic compression.

Final Open Panel Discussion. The panel discussed question eight, which was intended by CMS as a non-voting question. The specific areas of discussion are contained in the transcript of the meeting.

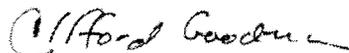
Adjournment. The meeting adjourned at 4:11 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development &
Coverage Advisory Committee on
November 18, 2009, and that these minutes
accurately reflect what transpired.



Maria A. Ellis
Executive Secretary, MEDCAC, CMS

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



Clifford Goodman, Ph.D.
Chairperson