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

October 6, 2005

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

Medicare Coverage Advisory Committee

October 6, 2005

Attendees

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

Kimberly Long
Executive Secretary

Voting Member/Patient Advocate
Leslie B. Fried, J.D.

Voting Members
Lishan Aklog, M.D.
Marc L. Berger, M.D.
Kim J. Burchiel, M.D.
Harry B. Burke, M.D., Ph.D.
Robert H. Christenson, Ph.D.
Mark Fendrick, Ph.D.
Robert S. McDonough, M.D.
Alexander Emyr Khan Ommaya, Sc.D., M.A.
Deborah Shatin, Ph.D.

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

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

Consumer Representative
Linda A. Bergthold, Ph.D.

Guest Expert Panelists
Joh S. Kirkpatrick, M.D., F.A.C.S.
Sean D. Sullivan, Ph.D.
Kenneth Koval, M.D.
Barbara D. Boyan, Ph.D.

Thursday, October 6, 2005, 8:18 a.m.

The Medicare Coverage Advisory Committee met on October 6, 2005, to discuss the evidence, hear presentations and public comment, and make recommendations regarding the treatments for bone fractures that fail to progress to union.

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

CMS Summary and Presentation of Voting Questions. A CMS representative presented the panel with a general overview of the agenda for the meeting, introducing the presenters, and showing the panelists and audience the eight general questions that would be voted on at the end of the meeting.

Presentation of the Technology Assessment. Dr. Karen Schoelles presented a summary of the technology assessment performed by the evidence-based practice center and health technology group at ECRI. Following her presentation she responded to questions from the panelists.

Presentations. The panel heard presentations by Dr. David B. Carmack and Dr. Alan L. Jones. Dr. Cormack addressed the use of electrical stimulation and ultrasound in the treatment of nonunion fractures, while Dr. Jones focused his presentation on the use of otrthobiologics for the treatment. At the end of each presentation, the panelists were given the opportunity to ask questions.

Scheduled Public Comments. Seven speakers addressed the panel concerning various treatment modalities for use in nonunion fractures. Six of the seven were orthopedic surgeons, three of whom were making statements on behalf of manufacturers. One speaker was an employee of a manufacturer.

Questions to Presenters. The panel was given the opportunity to pose questions to the presenters, and those who had made scheduled comments.

Open Public Comments. Two additional speaker, one a treating orthopedic surgeion, the other representing a manufacturer, addressed the panel.

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

Final Remarks and Vote.

Following discussion, including amending and deleting some of the original questions presented, the panel voted on the following questions with results as indicated:

QUESTION 1: How well does the evidence support well-defined indication for the use of these technologies in the treatment of nonunion fracture, going from one, poorly, to five, very well?

Ultrasound without surgery. Of the voting members, six voted two, four voted three ; of nonvoting members, three voted two, three voted three.

Ultrasound with surgery. Of the voting members, seven voted two, three voted three; of nonvoting members, four voted two, one voted three, and one voted four.

Internal electrical stimulation. Of the voting members, four voted one, five voted two and one voted three; of the nonvoting members, one voted one, three voted two, one voted three, and one voted four.

EC without surgery. Of the voting members, eight voted two, one voted three and one voted four; of the nonvoting members, three voted two, one voted three, one voted four, and one voted five.

EC with surgery. Of the voting members, eight voted two and two voted three; of the nonvoting members, three voted two, two voted three, and one voted four.

PEMF with surgery. Of the voting members, four voted two and six voted three; of the nonvoting members, two voted two, three voted three, and one voted five.

PEMF without surgery. Of the voting members, three voted two, six voted three, and one voted four; of the nonvoting members, one voted two, three voted three, and two voted five.

DBM. Of the voting members, five voted one and five voted two; of the nonvoting members, five voted two and one voted four.

BMP-7. Of the voting members, one voted two, five voted three, three voted four, and one voted five; of the nonvoting members, one voted two, three voted three, one voted four, and one voted five.

BMP-2. Of the voting members, seven voted one, two voted two, and one voted three; of the nonvoting members, one voted one, two voted two, one voted three, and two voted four.

QUESTION 2: How confident are you in the validity of the scientific data for biophysical enhancement in nonunion treatments on the following outcomes?

Ultrasound with surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, three voted one, one voted two, one voted three, two voted four, and three voted five; of the nonvoting members, one voted two, four voted three, and one voted four.

Radiographic healing. Of the voting members, nine voted two and one voted three; of the nonvoting members, two voted two, two voted three, and two voted four.

Clinical healing. Of the voting members, one voted one, eight voted two, and one voted three; of the nonvoting members, three voted two, two voted three, and one voted four.

Radiographic healing and clinical healing. Of the voting members, one voted one, eight voted two, and one voted three; of the nonvoting members, three voted two, two voted three, and one voted four.

Ultrasound without surgery, as to.

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, three voted three, two voted four, and four voted five; of the nonvoting members, two voted three, three voted four, and one voted five.

Radiographic healing. Of the voting members, one voted one, six voted two, and one voted three; of the nonvoting members, two voted two, one voted three, and three voted four.

Clinical healing. Of the voting members, two voted one, six voted two, and two voted three; of the nonvoting members, three voted two, one voted three, and two voted four.

Radiographic healing and clinical healing. Of the voting members, one voted one, six voted two, and three voted three; of the nonvoting members, two voted two, two voted three, and two voted four.

Internal electrical, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, four voted one, one voted two, and five voted three; of the nonvoting members, one voted one, three voted two, one voted three, and one voted four.

Radiographic healing. Of the voting members, one voted one, seven voted two, and one voted three; of the nonvoting members, one voted one, three voted two, one voted three, and one voted four.

Clinical healing. Of the voting members, one voted one, seven voted two, and two voted three; of the nonvoting members, four voted two, one voted three, and one voted four.

Radiographic healing and clinical healing. Of the voting members, one voted one, eight voted two, and one voted three; of the nonvoting members, four voted two, one voted three, and one voted four.

EC without surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, two voted one, one voted two, two voted three, three voted four, and two voted five; of the nonvoting members, one voted two, two voted three, one voted four, and two voted five.

Radiographic healing. Of the voting members, six voted two, three voted three, and one voted four; of the nonvoting members, three voted two, one voted three, one voted four, and one voted five.

Clinical healing. Of the voting members, six voted two, three voted three, and one voted tour; of the nonvoting members, four voted two, one voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, seven voted two, two voted three, and one voted four; of the nonvoting members, four voted two, one voted four, and one voted five.

EC with surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, two voted one, two voted two, two voted three, two voted four, and two voted five; of the nonvoting members, one voted two, two voted three, one voted four, and two voted five.

Radiographic healing. Of the voting members, seven voted two, two voted three, and one voted four; of the nonvoting members, three voted two, one voted three, one voted four, and one voted five.

Clinical healing. Of the voting members, eight voted two and two voted three; of the nonvoting members, four voted two, one voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, one voted one, seven voted two, and two voted three; of the nonvoting members, four voted two, one voted four, and one voted five.

PEMF with surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting

members, two voted one, two voted two, two voted three, two voted four, and two voted five; of the nonvoting members, two voted three, two voted four, and two voted five.

Radiographic healing. Of the voting members, two voted two, six voted three, and two voted four; of the nonvoting members, one voted two, one voted three, three voted four, and one voted five.

Clinical healing. Of the voting members, four voted two and six voted three; of the nonvoting members, three voted three, two voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, four voted two, five voted three, and one voted four; of the nonvoting members, three voted three, two voted four, and one voted five.

PEMF without surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, two voted one, one voted two, one voted three, two voted four, and four voted five; of the nonvoting members, two voted four and four voted five.

Radiographic healing. Of the voting members, two voted two, five voted three, and three voted four; of the nonvoting members, one voted two, one voted three, three voted four, and one voted five.

Clinical healing. Of the voting members, one voted one, two voted two, five voted three, and two voted four; of the nonvoting members, two voted three , three voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, one voted one, two voted two, four voted three, and three voted four; of the nonvoting members, two voted three, three voted four, and one voted five.

DBM, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, five voted one, two voted two, and three voted three; of the nonvoting members, two voted one, two voted two, one voted three, and one voted four.

Radiographic healing. Of the voting members, one voted one, eight voted two, and one voted three; of the nonvoting members, one voted one, three voted two, one voted three, and one voted four.

Clinical healing. Of the voting members, two voted one and eight voted two; of the nonvoting

members, four voted two, one voted three, and one voted four.

Radiographic healing and clinical healing. Of the voting members, two voted one and eight voted two; of the nonvoting members, four voted two, one voted three, and one voted four.

BMP-7, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, four voted two, two voted three, two voted four, and one voted five; of the nonvoting members, two voted three, three voted four, and one voted five.

Radiographic healing. Of the voting members, seven voted three and three voted four; of the nonvoting members, one voted two, three voted three, one voted four, and one voted five.

Clinical healing. Of the voting members, one voted two, six voted three, and three voted four; of the nonvoting members, two voted three, three voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, two voted two, five voted three, and three voted four; of the nonvoting members, two voted three, three voted four, and one voted five.

BMP-2, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, four voted one, three voted two, and three voted three; of the nonvoting members, one voted one, one voted two, three voted three, and one voted four.

Radiographic healing. Of the voting members, two voted one, five voted two, and three voted three; of the nonvoting members, two voted one, two voted two, one voted three, and one voted four.

Clinical healing. Of the voting members, two voted one, six voted two, and two voted three; of the nonvoting members, one voted one, three voted two, one voted three, and one voted four.

Radiographic healing and clinical healing. Of the voting members, three voted one, six voted two, and one voted three; of the nonvoting members, one voted one, three voted two, one voted three, and one voted four.

QUESTION 3: How likely is it that the following treatments for nonunion fractures will positively affect the following health outcomes, where the outcome is causally related to the respective biophysical enhancement?

Ultrasound with surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, three voted two, one voted four, and five voted five; of the nonvoting members, one voted one, one voted two, one voted three, and three voted five.

Radiographic healing. Of the voting members, five voted two, two voted three, and three voted four; of the nonvoting members, two voted two, one voted three, and three voted four.

Clinical healing. Of the voting members, six voted two, two voted three, and one voted four; of the nonvoting members, two voted two, two voted three, and two voted four.

Radiographic healing and clinical healing. Of the voting members, one voted one, six voted two, two voted three, and one voted four; of the nonvoting members, two voted two, two voted three, and two voted four.

Ultrasound without surgery, as to.

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one had no vote, one voted one, two voted two, and six voted five; of the nonvoting members, two voted three, three voted four, and one voted five.

Radiographic healing. Of the voting members, one had no vote, three voted two, three voted three, and three voted four; of the nonvoting members, one voted two, two voted three, and three voted four.

Clinical healing. Of the voting members, one had no vote, four voted two, three voted three, and two voted four; of the nonvoting members, one voted two, three voted three, and two voted four.

Radiographic healing and clinical healing. Of the voting members, one had no vote, four voted two, three voted three, and two voted four; of the nonvoting members, one voted two, three voted three, and two voted four.

Internal electrical, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, four voted two, two voted three, and three voted four; of the nonvoting members, one voted one, two voted two, two voted three, and one voted four.

Radiographic healing. Of the voting members, eight voted two and two voted three; of the nonvoting members, one voted one, three voted two, and two voted four.

Clinical healing. Of the voting members, eight voted two and two voted three; of the nonvoting members, one voted one, one voted two, two voted three, and two voted four.

Radiographic healing and clinical healing. Of the voting members, one voted one, seven voted two, and two voted three; of the nonvoting members, one voted one, one voted two, two voted three, and two voted four.

EC without surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, three voted two, one voted three, two voted four, and three voted five; of the nonvoting members, two voted two and four voted four.

Radiographic healing. Of the voting members, four voted two, four voted three, and two voted four; of the nonvoting members, two voted two, one voted three, two voted four, and one voted five.

Clinical healing. Of the voting members, four voted two, five voted three, and one voted tour; of the nonvoting members, two voted two, one voted three, two voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, one voted one, three voted two, five voted three, and one voted four; of the nonvoting members, two voted two, one voted three, two voted four, and one voted five.

EC with surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, three voted two, one voted three, three voted four, and two voted five; of the nonvoting members, four voted three and two voted four.

Radiographic healing. Of the voting members, four voted two, four voted three, and two voted four; of the nonvoting members, three voted three and three voted four.

Clinical healing. Of the voting members, six voted two, three voted three, and one voted four; of the nonvoting members, one voted two, two voted three, and three voted four.

Radiographic healing and clinical healing. Of the voting members, seven voted two, two voted three, and one voted four; of the nonvoting members, three voted three and three voted four.

PEMF with surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, three voted two, one voted three, two voted four, and three voted five; of the nonvoting members, one voted three, four voted four, and one voted five.

Radiographic healing. Of the voting members, two voted two, five voted three, and three voted four; of the nonvoting members, one voted two, one voted three, three voted four, and one voted five.

Clinical healing. Of the voting members, three voted two, six voted three, and one voted four; of the nonvoting members, two voted three, three voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, four voted two, five voted three, and one voted four; of the nonvoting members, two voted three, three voted four, and one voted five.

PEMF without surgery, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one had no vote, two voted two, one voted three, one voted four, and five voted five; of the nonvoting members, one voted one, three voted two, one voted four, and one voted five.

Radiographic healing. Of the voting members, one had no vote, two voted two, three voted three, and four voted four; of the nonvoting members, one voted three, three voted four, and two voted five.

Clinical healing. Of the voting members, one had no vote, two voted two, four voted three, and three voted four; of the nonvoting members, one voted three , two voted four, and three voted five.

Radiographic healing and clinical healing. Of the voting members, one had no vote, two voted two, four voted three, and three voted four; of the nonvoting members, one voted three, two voted four, and three voted five.

DBM, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one had no vote, one voted two, five voted three, and three voted four; of the nonvoting members,

two voted three, three voted four, and one voted five.

Radiographic healing. Of the voting members, one had no vote, one voted one, six voted two, and two voted three; of the nonvoting members, four voted two, one voted three, and one voted four.

Clinical healing. Of the voting members, one had no vote, one voted one, six voted two, and two voted three; of the nonvoting members, three voted two, two voted three, and one voted four.

Radiographic healing and clinical healing. Of the voting members, one had no vote, one voted one, six voted two, and two voted three; of the nonvoting members, three voted two, two voted three, and one voted four.

BMP-7, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, two voted two, four voted three, one voted four, and two voted five; of the nonvoting members, three voted three, two voted four, and one voted five.

Radiographic healing. Of the voting members, six voted three and four voted four; of the nonvoting members, three voted three, two voted four, and one voted five.

Clinical healing. Of the voting members, seven voted three and three voted four; of the nonvoting members, three voted three, two voted four, and one voted five.

Radiographic healing and clinical healing. Of the voting members, one voted two, six voted three, and three voted four; of the nonvoting members, two voted three, three voted four, and one voted five.

BMP-2, as to:

Morbidity (i.e., infection, amputation, permanent loss of limb function). Of the voting members, one voted one, four voted two, four voted three, and one voted four; of the nonvoting members, one voted one, three voted three, one voted four, and one voted five.

Radiographic healing. Of the voting members, three voted one, four voted two, and three voted three; of the nonvoting members, one voted two, three voted three, and two voted five.

Clinical healing. Of the voting members, two voted one, five voted two, and three voted three; of the nonvoting members, two had no votes, one voted two, two voted three, and one voted five.

Radiographic healing and clinical healing. Of the voting members, two voted one, six voted two, and two voted three; of the nonvoting members, two voted two, two voted three, and two voted five.

QUESTION 4: How confident are you that the following technologies will produce a clinically important net health benefit for patients with a nonunion fracture?

Ultrasound without surgery. Of the voting members, six voted two and four voted three; of the nonvoting members, one voted two, two voted three, two voted four, and one voted five.

Ultrasound with surgery. Of the voting members, four voted two, three voted three, and three voted four; of the nonvoting members, one voted two, two voted three, and three voted four.

Internal electric stimulation. Of the voting members, one voted one, seven voted two, and two voted three; of the nonvoting members, three voted two, one voted three, and one voted four.

EC without surgery. Of the voting members, five voted two and five voted three; of the nonvoting members, three voted two, two voted three, and one voted four.

EC with surgery. Of the voting members, four voted two, four voted three, and two voted four; of the nonvoting members, two voted two, two voted three, and two voted four.

PEMF with surgery. Of the voting members, three voted two and seven voted three; of the nonvoting members, four voted three, one voted four, and one voted five.

PEMF without surgery. Of the voting members, three voted two, two voted three, and five voted four; of the nonvoting members, three voted three, one voted four, and two voted five.

DBM. Of the voting members, one had no vote, three voted one, four voted two, and two voted three; of the nonvoting members, one voted two, four voted three, and one voted four.

BMP-7. Of the voting members, one had no vote, one voted two, three voted three, four voted four, and one voted five; of the nonvoting members, one voted three, three voted four, and two voted five.

BMP-2. Of the voting members, one had no vote, three voted one, two voted two, three voted three, and one voted four; of the nonvoting members, one voted one, one voted two, two voted three, and two voted five.

QUESTION 5. It was the consensus of the panel that this question had been addressed in other questions previously voted on; therefore, no vote was taken on number five.

QUESTION 6. How confident are you that the improved net health outcomes will hold for the off-label treatments of nonunion fractures using orthobiologic devices? Of the voting members, two voted one, six voted two, and two voted three; of the nonvoting members, four voted one, one voted two, and voted four.

QUESTION 7. How likely is it that completely healed nonunion fractures resulting from these treatments can be generalized to:

Fracture types for which there are no clinical studies: Of the voting members, two voted two, seven voted three, and one voted four; of the nonvoting members, four voted three and two voted four.

Providers (facilities/physicians) practice: Of the voting members, two voted two, six voted three, one voted four, and one voted five; of the nonvoting members, two voted two, three voted three, and one voted four.

Medicare population: Of the voting members, two voted two, five voted three, and three voted four; of the nonvoting members, two had no votes, two voted three, and two voted four.

QUESTION 8. How confident are you that orthobiologics are equivalent in the treatment of nonunion fractures? Of the voting members, one had no vote, six voted one, and three voted two; of the nonvoting members, four voted one, one voted two, and one voted three.

QUESTION 9. How confident are you that Bone Morphogenic Protein 2 and Bone Morphogenic Protein 7 are equivalent in the treatment of nonunion fractures? Of the voting members, two had no votes, four voted two, and four voted three; of the nonvoting members, four voted two, and two voted four.

Adjournment. The meeting adjourned at 4:17 p.m.

I certify that I attended the meeting of the Executive Committee on October 6, 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.

Barbara J. McNeil

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