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

July 14, 2004

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland

Medicare Coverage Advisory Committee

July 14, 2004

Attendees

Ronald M. Davis, M.D.
Chairperson

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

Michelle Atkinson
Executive Secretary

Voting Members
Edgar R. Black, M.D.
Steven N. Goodman, M.D., M.H.S., Ph.D.
David J. Cohen, M.D., M.Sc.
Lishan Aklog, M.D.

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

Consumer Representative
Charles J. Queenan, III

Industry Representative
Michael Lacey, M.Sc.

Guest Panelists
Joel Cooper, M.D.
Eric A. Rose, M.D.

Wednesday, July 14, 2004, 8:07 a.m.

The Medicare Coverage Advisory Committee met on July 14, 2004, to discuss

and make recommendations concerning the quality of the evidence and related issues for

the use of transmyocardial revascularization (TMR), TMR + coronary artery bypass

grafting (CABG) and percutaneous myocardial revascularization (PMR) to treat severe

angina.

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. A CMS

representative presented the panel with information on Medicare coverage policy related

to the technologies, FDA label information, and presented the questions that the panel

would be asked to vote upon at the conclusion of this meeting.

Following this presentation, Dr. Davis informed the panel and the public that the format

of the questions and voting procedure had changed from prior MCAC meetings.

AHRQ Presentation of Technology Assessment   Dr. Deborah Zarin presented a

summary of the evidence review conducted by the Duke University Evidence-Based

Practice Center. Following her presentation, the panel was given the opportunity to ask

questions.

Requestor's Presentation. Representatives from Society of Thoracic Surgeons,

Cardiogenesis, PLC, and Edwards Lifesciences presented the panel with information on

the STS database, clinical results from treatment with TMR, results and analyses of

different randomized and observational studies, asserting that the use of TMR alone or as

an adjunct to CABG, is of favorable clinical significance and does lead to better health

outcomes when compared to CABG alone. It was also argued that PMR, although the

evidence concerning its use is not as strong as that of TMR, does show promise and

further studies are warranted. Following these presentations, the panel engaged in

lengthy questions of the presenters.

A representative from the American College of Cardiology addressed the panel, stating

ACC's position that use of TMR plus CABG would produce a clinically important net

health benefit for selected patients with chronic refractory angina, and that the data would

be applicable to the Medicare population. Concerning PMR, the ACC's position is that

the emerging body of evidence suggests that in selected individuals there is a moderate

degree of confidence that this is a helpful technique; however, there does not seem to be

any mortality benefit currently shown either in the short term or the long term, and they

await further data.

A community cardiothoracic surgeon presented the panel with a clinical study addressing

30-day outcomes of TMR plus CABG, concluding that TMR plus CABG as compared to

CABG alone in very carefully selected patients is associated with a reduced intensive

care unit stay, postoperative lengths of stay, postoperative atrial fibrillation, and may also

provide a benefit for operative survival, as well as rehospitalizations.

The panel posed questions to the ACC representative and the community cardiothoracic

surgeon.

Open Public Comments. Four speakers addressed the panel, including three Medicare

beneficiaries who had received TMR. All three noted the significant positive change the

treatment had made in their cases.

The fourth speaker was the director and chief research analyst of ECRI, who highlighted

some of the points made in the ECRI report that was provided to the panel.

Open Panel Discussion.   Following a lunch break, the panel engaged in a general

discussion, followed by discussion specific to each of the three categories, TMR alone,

TMR plus CABG, and PMR, prior to voting on each therapy.

Final Remarks and Vote.

The panel voted on the following questions:

TMR.

Question 1. For TMR alone, how well does the evidence address the effectiveness of

TMR in the treatment of chronic refractory angina in study patients for whom other

methods of revascularization are contraindicated?   Four voting members indicated a

moderate effectiveness (level 3) and one voting member indicated a moderate to

complete effectiveness (level 4).

Question 2a. How confident are you in the validity of the scientific data for this

outcome, concerning:

Short-term mortality? Two voting members indicated a moderate confidence

(level 3), and three voting members indicated a moderate to complete confidence (level

4).

Long-term survival? One voting member indicated none to moderate confidence

(level 2) and four voting members indicated moderate confidence (level 3).

Morbidity? Two voting members indicated a moderate confidence (level 3) and three voting members indicated a moderate to complete confidence (level 4).

Quality of life? Four voting members indicated a moderate confidence (level 3) and one voting member indicated a moderate to complete confidence (level 4).

Question 2b. How likely is it that TMR will improve this outcome compared to usual care:

Short-term care? Four voting members indicated not likely (level 1) and one voting member indicated not likely to reasonably likely (level 2).

Long-term survival? Four voting members indicated not likely (level 1) and one voting member indicated not likely to reasonably likely (level 2).

Morbidity? Two voting members indicated a reasonably likelihood (level 3), two voting members indicated a reasonable to complete likelihood (level 4), and one voting member indicated a complete likelihood (level 5).

Quality of life? Three voting members indicated a reasonable likelihood (level 3) and two voting members indicated a reasonable to complete likelihood (level 4).

Question 3. One voting member indicated no to moderate confidence (level 2), two voting members indicated moderate confidence (level 3), and two voting members indicated moderate to high confidence (level 4).

Question 4. Based on the literature presented, how likely is it that the results of TMR in the treatment of chronic medically refractory angina can be generalized to:

The Medicare population (aged 65+)? Two voting members indicated a reasonable to very likely likelihood (level 4) and three voting members indicated a very likely likelihood.

Providers (facilities/physicians) in community practice? Three voting members

indicated none to reasonably likelihood (level 2), one voting member indicated a

reasonable likelihood (level 3), and one voting member indicated a reasonable to very

likely likelihood (level 4).

TMR + CABG

Before voting on these questions, the panel stated that their responses would be addressed

to modified forms of questions 1 and 3, as follows:

Question 1. How well does the evidence address the effectiveness of TMR plus CABG

in the treatment of chronic refractory angina in study patients for whom complete

revascularization cannot be obtained by conventional means, i.e., CABG or PCI?   Two

voting members indicated limited confidence (level 1), one voting member indicated

limited to moderate confidence (level 2), and two voting members indicated moderate

confidence (level 3).

Question 2b. How confident are you in the validity of the scientific data for this

outcome:

Short-term mortality? Three panel members indicate no to moderate confidence (level

2), and two voting members indicated moderate confidence (level 3).

Long-term survival? One voting member indicated no confidence (level 1), two voting

members indicated no to moderate confidence (level 2), and two voting members

indicated moderate confidence (level 3).

Morbidity? One voting member indicated no confidence (level 1), three voting members

indicated moderate confidence (level 3), and one voting member indicated moderate to

complete confidence (level 4).

Quality of life? Two voting members indicated no to moderate confidence (level 2), two voting members indicated moderate confidence (level 3), and one voting member indicated moderate to high confidence (level 4).

Question 2b. How likely is it that TMR plus CABG will improve this outcome compared to usual care:

Short-term mortality? Four voting members indicated none to reasonable likelihood (level 2), and one voting member indicated reasonable to very likely likelihood (level 4).

Long-term survival? Three voting members indicated not likely (level 1), one voting member indicated none to reasonable likelihood (level 2), and one voting member indicated reasonable likelihood (level 3).

Morbidity? Four voting members indicated none to reasonable likelihood (level 2), and one voting member indicated reasonable likelihood (level 3).

Quality of life? One voting member indicated not likely (level 1), three voting members indicated none to reasonable likelihood (level 2), and one voting member indicated reasonable likelihood (level 3).

Question 3. How confident are you that TMR plus CABG will produce a clinically important net health benefit in the treatment of chronic refractory angina in study patients, in study patients for whom complete revascularization cannot be obtained by conventional means, i.e., CABG or PCI? One voting member indicated no confidence (level 1), three voting members indicated no to moderate confidence (level 2), and one voting member indicated moderate to high confidence (level 4).

Question 4. Based on the literature presented, how likely is it that the results of TMR plus CABG in the treatment of chronic refractory angina can to be generalized to:

The Medicare population (aged 65 +)? Three voting members indicated reasonable likelihood (level 3), and two voting members indicated reasonable to very likely likelihood (level 5).

Providers (facilities/physicians) in community practice? Three voting members indicated no to reasonable likelihood (level 2), one voting member indicated reasonable likelihood (level 3), and one voting member indicated very likely (level 5).

PMR

Question 1. How well does the evidence address the effectiveness of PMR in the treatment of chronic refractory angina in study patients for whom other methods of revascularization are contraindicated? Two voting members indicated limited (level 1), one voting member indicated limited to moderate (level 2), one voting member indicated moderate (level 3), and one voting member indicated moderate to complete (level 4).

Question 2a. How confident are you in the validity of the scientific data for this outcome:

Short-term mortality? Two voting members indicated no to moderate confidence (level 2), one voting member indicated moderate confidence (level 3), and two voting members indicated moderate to high confidence (level 4).

Long-term survival? One voting member indicated no confidence (level 1), and four voting members indicated no to moderate confidence (level 2).

Morbidity? Four voting members indicated no to moderate confidence (level 2), and one member indicated moderate confidence (level 3).

Quality of life? The voting members were unanimous indicating no to moderate confidence (level 2).

Question 2b. How likely is it that PMR will improve this outcome compared to usual care:

Short-term mortality? The voting members were unanimous indicating not likely (level 1).

Long-term survival? The voting members were unanimous indicating not likely (level 1).

Morbidity? Four voting members indicated not likely to reasonable likelihood (level 2), and one voting member indicated reasonable likelihood (level 3).

Quality of life? The voting members were unanimous indicating not likely to reasonable likelihood (level 2).

Question 3. How confident are you that PMR will produce a clinically important net health benefit in the treatment of chronic refractory angina in study patients for whom other conventional methods of revascularization are contraindicated? Two voting members indicated no confidence (level 1) and three voting members indicated no to moderate confidence (level 2).

Question 4. Based on the literature presented, how likely is it that the results of PMR in the treatment of chronic medically refractory angina can be generalized to:

The Medicare population aged 65 and older? Three voting members indicated reasonably likely (level 3) and two voting members indicated reasonably to very likely (level 4).

Providers (facilities/physicians) in community practice? Four voting members indicated not likely to reasonably likely (level 2) and one voting member indicated reasonably likely (level 3).

Adjournment. The meeting adjourned at 3:25 p.m.

I certify that I attended the meeting of the Executive Committee on July 14, 2004, and that these minutes accurately reflect what transpired.

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Michelle Atkinson
Executive Secretary, MCAC, CMS

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

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Ronald M. Davis, M.D.
Chairperson