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

October 21, 2009

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

Medicare Evidence Development & Coverage Advisory Committee

October 21, 2009

Attendees

Clifford Goodman, Ph.D. Chairperson

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

Maria A. Ellis Executive Secretary

Voting Members
Virginia C. Calega, M.D., M.B.A.
Mark D. Carlson, M.D., M.A.
Gregory J. Dehmer, M.D.
Mercedes K.C. Dullum, M.D.
William H. Maisel, M.D., M.P.H.
Mauro Moscucci, M.D.
Craig Umscheid, M.D., M.S.C.E.

<u>CMS Liaison</u> Marcel Salive, M.D.

Industry Representative Neal Thomas, Ph.D.

Patient Advocate
Phyllis Atkinson, R.N., M.S., GNP-BC

Guest Panel Members
Stephen C. Hammill, M.D., F.A.C.C., F.H.R.S.
Douglas L. Packer, M.D.

Guest Speaker Yves D. Rosenberg, M.D., M.P.H.

Wednesday, October 21, 2009, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on October 21, 2009, to discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of catheter ablation for the treatment of atrial fibrillation.

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

<u>CMS Presentation of Voting Questions.</u> A CMS representative presented the panel and audience with the questions to be considered and discussed or voted on by the panel.

<u>Presentation by Guest Speaker</u>. The panel heard a presentation from Dr. Rosenberg addressing the etiology and history of treatment for atrial fibrillation. Following his presentation, the panel was allowed to ask him questions concerning topics he addressed.

<u>Presentation of Technology Assessment.</u> The panel heard the results of the technology assessment conducted by the Tufts Medical Center Institute of Clinical Research and Health Policy Studies. Following the presentation, the panel asked questions of the presenters concerning the assessment.

<u>Scheduled Public Comments.</u> The panel heard from five speakers addressing issues surrounding the use of catheter ablation, including recent and about-to-be-published studies. The speakers included both industry and professional society representatives.

<u>Questions to Presenters and Open Panel Discussion</u>. There was an extensive questioning period where the panel was given the opportunity to pose questions to the presenters.

<u>Initial Open Panel Discussion.</u> The panel conducted an extensive discussion on each of the discussion questions posed by CMS in the area of clinical comparators, population, outcomes, device characteristics and physician training. This discussion included input from the chair, members of the panel, and the presenters.

Formal Open Panel Discussion. The panel turned its attention to the voting questions, having additional discussion on each one before their vote. Of significance was that the panel decided to vote on four separate subparts to Question 1 and Question 5, as follows: A, recurrence of arrhythmia; B, symptom relief, including quality of life factors; C, incidence of stroke; and D, survival. After discussion of each question and its subparts, the panel then voted. The results of the voting were shown to the public on cards and recorded by staff.

Adjournment. The meeting adjourned at 3:53 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on October 21, 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.

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Clifford Goodman, Ph.D.

Chairperson