

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

**November 17, 2010**

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

**Medicare Evidence Development & Coverage Advisory Committee**

**November 17, 2010**

**Attendees**

Clifford Goodman, Ph.D.  
Chairperson

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

Maria A. Ellis  
Executive Secretary

Voting Members

Helen Darling, M.A.  
Roger Dmochowski, M.D.  
Dale Fuller, M.D.  
Karl Matuszewski, M.S., Pharm.D.  
David M. Mintzer, M.D.  
Pearl Moore, R.N., M.N., F.A.A.N.  
Louis Potters, M.D., F.A.C.R.  
Kevin Schulman, M.D., M.B.A.  
Robert L. Steinbrook, M.D.

CMS Liaison

James Rollins, M.D.

Industry Representative

G. Gregory Raab, Ph.D.

Guest Panel Members

Ravi A. Madan, M.D.  
Mitchell Howard Sokoloff, M.D., F.A.C.S.

Invited Guest Speaker

James L. Gulley, M.D., Ph.D., F.A.C.P.

**Wednesday, November 17, 2010, 8:14 a.m.**

The Medicare Evidence Development & Coverage Advisory Committee met on November 17, 2010, to discuss the evidence, hear presentations and public comment, and make recommendations concerning currently available evidence regarding the clinical benefits and harms of on-label and off-label use of autologous immunotherapy treatment of metastatic prostate cancer.

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

**CMS Presentation of Voting Questions.** A CMS representative presented the panel and audience with an explanation of the voting scale to be used, and the voting and discussion questions that would be considered by the panel.

**Presentation by Invited Guest Speaker.** The panel heard a presentation from Dr. James Gulley, from the Center for Cancer Research at NCI, providing an overview of metastatic prostate cancer including definitions, symptoms and severity of symptoms of the disease, and available treatment options that are currently FDA approved.

**Presentation of Technology Assessment.** The panel heard a presentation from a senior scientist at the Blue Cross Blue Shield Technology Evaluation Center concerning their technology assessment performed under contract to AHRQ. Following the presentation, there was limited time for the panelists to question the presenter before moving on to public comments.

**Scheduled Public Comments.** The panel heard from a total of nine scheduled speakers, including a prostate cancer patient's surviving grandson, clinicians, professional society representatives, patient advocacy group representatives, research investigators, and one manufacturer's chief medical officer.

**Open Public Comments.** The panel heard from 13 members of the public, including patients, family members, advocacy group representatives and clinicians.

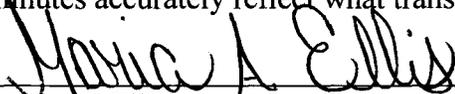
**Questions to Presenters.** The panel was given the opportunity to pose questions to the presenters.

**Open Panel Discussion and Voting Questions.** The panel conducted discussion on each of the voting questions posed by CMS, followed by a vote on the respective question. The votes were announced by individual panelists, are included in the transcript, were recorded by staff, and were cast by the panelists using automated devices as well in writing on their respective voting sheets, which were also collected by staff.

**Final Open Panel Discussion.** After resolution of the voting questions, the panel discussed questions seven, eight and nine, the non-voting questions.

**Adjournment.** The meeting adjourned at 4:20 p.m.

I certify that I attended the meeting  
of the Medicare Evidence Development  
& Coverage Advisory Committee  
on November 17, 2010, and that these  
minutes accurately reflect what transpired.

  
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Maria A. Ellis  
Executive Secretary, MEDCAC, CMS

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



Clifford Goodman, Ph.D.  
Chairperson