



Heart House  
9111 Old Georgetown Rd.  
Bethesda, MD 20814-1699  
USA

(301) 897-5400  
(800) 253-4636  
Fax: (301) 897-9745  
[www.acc.org](http://www.acc.org)

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March 29, 2006

Madeline Ulrich, M.D., M.S.  
Medical Officer  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD

Dear Dr. Ulrich:

The American College of Cardiology (ACC) is pleased to offer comments on the reconsideration of Medicare's National Coverage Determination for electrical bioimpedance for cardiac output monitoring (CAG-00001R2). The ACC is a 33,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Members of the ACC's Heart Failure and Transplant Committee and Prevention Committee have reviewed the reconsideration request, along with the evidence submitted concerning use of thoracic electrical bioimpedance (TEB) in the management of patients with hypertension. We found that the evidence does not support establishment of national Medicare coverage as requested for hypertensive patients on one or more anti-hypertensive drugs who are not at goal blood pressure. Our clinical experts noted that the two small randomized studies cited by the requester focused only patients with blood pressure that was quite difficult to control. The patients were typically on multiple anti-hypertensive drugs and were, on average obese. These factors limit the extent to which the results of the studies can be generalized to the broader population of patients who have failed to achieve desired blood pressure control on only one or more antihypertensive drugs.

Letter to Madeline Ulrich, M.D., M.S. – (cont'd)  
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The studies cited do provide some evidence of benefit for a more narrowly defined patient population. The ACC believes that Medicare coverage for patients with drug resistant hypertension, defined as failure to achieve goal blood pressure when adhering to full doses of an appropriate three drug regimen, including a diuretic may be appropriate. We note that the current NCD already provides local Medicare carriers with the explicit discretion to coverage TEB for this patient population.

If you have any questions or if the ACC can be of any assistance, please contact Rebecca Kelly, Director of Regulatory Affairs by telephone at 301-493-2398 or by e-mail at [rkelly@acc.org](mailto:rkelly@acc.org).

The ACC appreciates CMS' willingness to work cooperatively with the physician community to develop appropriate Medicare coverage policies. Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "Steven Nissan". The signature is written in a cursive, flowing style.

Steven Nissan, M.D., F.A.C.C.  
President