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**Heart House**

2400 N St., NW  
Washington, DC 20037-1153  
USA

202.375.6000  
800.253.4636  
Fax: 202.375.7000  
[www.acc.org](http://www.acc.org)

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Thomas E. Arend, Jr.

November 21, 2006

Lori Paserchia, MD  
Susan Harrison  
Sandra Jones, RN  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: Proposed National Coverage Decision (NCD) on Extracorporeal  
Photopheresis (CAG-00324R).

Dear Dr. Paserchia, Ms. Harrison and Ms. Jones:

The American College of Cardiology (ACC) appreciates the opportunity to comment on CMS' proposed National Coverage Decision (NCD) on Extracorporeal Photopheresis (CAG-00324R). The ACC is a 34,000 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.

The ACC strongly supports the coverage of extracorporeal photopheresis for patients with acute cardiac allograft rejection refractory to standard immunosuppressive treatments (indication #1 in the proposed decision memo). Although the number of transplant recipients that require this therapy is small, the data available have shown the treatment to be effective and to have minimal side effects in a patient population with few other possible treatment options (and in whom graft loss results in the death of the patient).

Although it doesn't affect the proposed coverage decision, the ACC would like to point out to CMS that a new grading system for endomyocardial biopsies has been published and adopted to replace the system developed by Billingham et. al. which is cited in the Disease Summary section II.B.1 of the proposed decision memo concerning extracorporeal photopheresis. Details of the new grading system can be found in *J Heart Lung Transplant* 2005; 24:1710-1720.

*The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.*

Our recommendation on this coverage issue is based on our knowledge of the most relevant and current clinical literature available. Our goal is to assist CMS in making appropriate coverage decisions based on scientific evidence. The ultimate judgment regarding care of a particular patient must be made by the physician and patient in light of all of the circumstances presented by the patient.

Again, the ACC appreciates the opportunity to comment on CMS' proposed National Coverage Decision on Extracorporeal Photopheresis. If you have any questions, please contact Rebecca Kelly, Director of Regulatory Affairs at 202.375.6398, or by e-mail at [rkelly@acc.org](mailto:rkelly@acc.org)

Sincerely,

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

Steven E. Nissen, M.D., F.A.C.C.  
President