

March 18, 2004

Steve Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244

Dear Dr. Phurrough:

On February 12, 2004, we submitted a letter to you requesting Medicare coverage of implantable cardioverter defibrillators (ICDs) for Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) patients. We recognized that the request would not be acted upon until the SCD-HeFT data was supplied, following the announcement of trial results at ACC on March 8, 2004. We are submitting this follow-up request to accompany the trial results that you received during our meeting today.

We are making a formal request for Medicare coverage of ICDs for SCD-HeFT patients, consistent with the results of the trial. We believe that the results of this landmark NIH study, a 23% reduction in all-cause mortality, ICDs vs. placebo ( $p=.007$ ), warrant full coverage of the SCD-HeFT patient population. We propose the inclusion of the SCD-HeFT patient population as a sixth covered indication in Section 35-85 *Implantable Automatic Defibrillators* of the Coverage Issues Manual. The proposed policy language is as follows:

Additional indications effective for services performed on or after October 1, 2004:

6. Documented congestive heart failure for greater than 3 months and a measured left ventricular ejection fraction  $\leq 0.35$  and a New York Heart Association Classification of II or III. Patients must not have a life expectancy of less than one year from any cause

Thank you for your consideration of this important matter.

Sincerely,

Bob Thompson, MS., MA.  
Director, Reimbursement, Economics and Health Policy

c. Marcell Salive, MD, Director, Division of Medical and Surgical Services  
JoAnna Baldwin, Lead Analyst