



Office of Clinical Standards and Quality/Coverage and Analysis Group

February 26, 2003

Anne Gosier
Guidant Corporation
1310 G Street, Northwest, Suite 770
Washington, D.C. 20005

Dear Ms. Gosier:

This is a request for Guidant Corporation to provide the Centers for Medicare and Medicaid Services (CMS) the complete data set for the Multicenter Automatic Defibrillator Trial II (MADIT II). We have received your email with the additional data field presented by Dr. Moss and Dr. Smith at the Medicare Coverage Advisory Committee (MCAC). As you know, CMS had requested this data on pre-trial electrophysiological (EP) study results several months prior to the MCAC meeting. The existence of that additional data field suggests that other pre-enrollment data may be available. We are requesting that data to address comments from presenters at the MCAC meeting who raised the question of potential preselection bias in referring patients into the trial. We are interested in exploring the characteristics of referred patients in an attempt to respond to that question.

General questions include:

1. What were the markers that referring physicians used to determine if a patient was an appropriate referral to a MADIT II clinical center?
2. What were the key factors that influenced physicians to obtain pre-trial EP studies in approximately 250 patients enrolled in the trial? Is there data on potential patients who were excluded from the trial by EP studies?
3. A myocardial infarction (MI) at least four weeks prior to enrollment was one of the requirements for patients to be eligible for the trial. The patients enrolled were an average of five years post-MI. What about these patients caused their cardiologist to refer them to the study so long after their MI and to not refer patients with more recent MIs?

We understand that complete data was not maintained on all patients considered for enrollment. However, we are interested in any data that you do have and request that you query your referring physicians to attempt to answer these questions.

We appreciate your continuing assistance in answering these questions as we proceed to expeditiously complete our coverage process. If you have questions please contact me at (410) 786-2281 or JoAnna Farrell at (410) 786-7205.

Sincerely,

Steve E. Phurrough, MD, MPA

Acting Director
Coverage and Analysis Group