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August 9, 2006

Madeline Ulrich, MD, MS
JoAnna Baldwin, MS
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore MD 21244

RE: National Coverage Analysis (NCA) on Ventricular Assist Devices (VADs) as Destination Therapy (CAG-00119R).

Dear Dr. Ulrich and Ms. Baldwin:

The American College of Cardiology (ACC) appreciates the opportunity to comment on CMS' first reconsideration of its National Coverage Analysis (NCA) on Ventricular Assist Devices (VADs) as Destination Therapy (CAG-00119R). 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.

In general, the ACC supports the adoption of JCAHO's proposed VAD Destination Therapy Certification criteria, although we believe some changes are necessary before final adoption by CMS. Following are ACC's recommendations for your consideration (suggested text revisions are in *italics* and underlined).

August 9, 2006

1. **Section DF.1:**

- A. ACC recommends that CMS add language to this section providing an exception for certain foreign-trained physicians and surgeons to serve as qualifying VAD physicians and surgeons. This exception would address circumstances where foreign-trained physicians and surgeons are appropriately qualified to care for VAD patients, but are not board-certified or even board-eligible due to training they received outside of the U.S. Language such as " . . . board-certified (or the foreign equivalent thereof) . . ." could accomplish this objective.
- B. ACC recommends revising the second bullet under the description of cardiologist qualifications by striking the reference to "recent experience" managing heart transplant patients as a potential criterion since we believe that having cared for heart transplants and not VAD recipients does not alone qualify one to be a VAD destination therapy cardiologist.

2. **Section DF.2:**

- A. The ACC recommends revising the sentence about acceptance criteria to read: "Acceptance criteria may include any or all of the following, as appropriate:"
- B. Under performance element 4, the ACC also recommends clarifying the third bullet by stating that this is required only if the patient is capable of performing the test, since many appropriate destination therapy candidates may be too ill to perform an exercise test or may not be able to perform the test due to orthopedic issues, etc.

Our recommendations on this coverage issue are 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' National Coverage Analysis on Ventricular Assist Devices as Destination Therapy. We would be happy to work with you on any of our recommendations. If you have any questions, please contact Rebecca Kelly, Director of Regulatory Affairs at 301.493.4398, or by e-mail at rkelly@acc.org.

Sincerely,



Steven E. Nissen, MD, F.A.C.C.
President