



# Heart Rhythm Society



October 28, 2004

Sean Tunis, MD, MSc.  
Chief Medical Officer  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Mail Stop S3-01-02  
Baltimore, MD 21244

Dear Dr. Tunis:

The Heart Rhythm Society (HRS) is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. The Heart Rhythm Society mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. The Heart Rhythm Society's 3,800 members are physicians, scientists and their support personnel who implant pacemakers and implantable cardioverter defibrillators (ICDs) in patients who require these life-saving devices.

The American College of Cardiology (ACC) is a 31,000 member non-profit professional medical society and teaching institution whose purpose 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 Heart Rhythm Society and the ACC welcome this opportunity to comment on the draft coverage decision by the Centers for Medicare and Medicaid Services (CMS) to extend coverage of Implantable Cardioverter Defibrillator (ICD) therapy for primary prevention of sudden cardiac death. Our response is based on the comprehensive and thoughtful analysis by CMS of the primary prevention trials and the conclusions drawn from this analysis. We commend CMS on the high quality of their careful review and the criticisms they raised. We applaud the decision to extend coverage for patients with coronary artery disease and to include those who have nonischemic cardiomyopathy.

The concerns raised by our societies focus on specific clinical criteria for coverage and the practical logistics of developing and maintaining a Registry. Our comments are summarized below:

1) **Ejection Fraction:** The benefit of primary prevention ICD therapy for patients with ischemic or nonischemic cardiomyopathy and left ventricular ejection fraction (LVEF)  $\leq 30\%$  is supported by the clinical data. Our members have expressed concern that the Sudden Cardiac

Death in Heart Failure Trial (SCD-HeFT) showed benefit for patients with LVEF of 35% or less, yet patients with LVEF 30-35% have been excluded from the coverage policy. The decision by CMS to exclude those with LVEF 30-35% is based on a subgroup analysis that the study was not designed to determine. HRS and ACC believe the Registry can be used to resolve this question. In the mean time, CMS should not exclude patients who met criteria for entry into the most comprehensive trial conducted to date.

**HRS and ACC recommend that the coverage decision be revised to include patients with LVEF of 35% or less.**

2) **Nine Month Interval for Non-Ischemic Cardiomyopathy**

SCD HeFT required patients to have stable Class II-III heart failure for 3 months prior to entry into the study. CMS has extended this interval to 9 months, ostensibly to exclude patients with a reversible nonischemic cardiomyopathy. This interval also allows time for patients to be treated with optimal medical therapy before considering implantable device therapy.

**HRS and ACC accept CMS' recommendation that patients have a diagnosis of nonischemic cardiomyopathy for >9 months prior to consideration of prophylactic ICD therapy.**

3) **Class IV Patients**

The COMPANION trial indicates that patients with Class IV heart failure who have received optimal medical therapy benefit from biventricular pacing. If cardiac resynchronization therapy is employed without an ICD (CRT-D) and the patient improves to NYHA Class III heart failure, then it will be necessary to upgrade the system from CRT to CRT-D. This exposes the patient to two procedures and ultimately increases the cost and risk of therapy. Therefore, patients with early Class IV heart failure who are receiving CRT therapy to improve them to Class III should receive a CRT-D device. HRS and ACC emphasize that CRT-D should be reserved for patients who do not respond to optimal medical therapy.

**HRS and ACC recommend that CMS consider extending coverage of CRT-D therapy to patients with early Class IV heart failure (not dependent on inotropic therapy) who have a reasonable expectation of improving to Class III. The proposed Registry could be used to assess the benefit of ICD therapy in patients with NYHA Class IV symptoms of heart failure.**

4) **Documented MI**

The CMS policy excludes patients with acute MI within 1 month or percutaneous transluminal coronary angioplasty within 3 months. We believe that patients with well documented remote MI and longstanding LV dysfunction (LVEF 35% or less), should not be excluded from ICD therapy if they are admitted with another MI or the need for a second PTCA. In such patients the

underlying disease is not reversible. They already met criteria for an ICD before their most recent admission.

**HRS and ACC recommend that coverage be extended to patients if they already met the criteria for an ICD prior to their most recent MI, CABG, or PTCA. We agree that patients who present with a new acute MI as the cause of left ventricular dysfunction should wait at least one month prior to ICD implantation.**

**5) Device Selection “shock only”**

HRS and ACC concur with CMS that single lead ICDs should be implanted for primary prevention therapy unless there are indications for dual chamber pacing or cardiac resynchronization therapy. We are concerned about the statement that ICDs should be "shock only" devices for primary prevention therapy. Prior clinical studies demonstrated that some patients require pacing after a shock is delivered. Moreover, anti-tachycardia pacing reduces exposure to painful shocks. The inclusion of anti-tachycardia pacing does not have an appreciable impact on the cost of the device. We conclude that this option should be available. The decision to program anti-tachycardia pacing into the arrhythmia termination algorithm should be left to the discretion of the physician. The reality is that all current devices manufactured by Guidant, Medtronic, and St. Jude incorporate anti-tachycardia algorithms. It would be unnecessary and potentially harmful to patients to deactivate this beneficial technology simply to meet the criteria for a "shock only" device.

**HRS and ACC recommend that the term “shock only” be removed from the coverage decision. The remainder of that paragraph regarding physician documentation of device selection is appropriate.**

**Additional Points of Agreement**

HRS and ACC concur that cardiogenic shock, irreversible brain damage, or other diseases that portend a poor prognosis (survival < 1 year) are contraindications to ICD therapy. We agree that LVEF must be documented by ventriculography, radionuclide scanning, echocardiography, magnetic resonance imaging or other cardiovascular imaging as appropriate. We also concur that defibrillation threshold testing is indicated at the time of ICD implantation.

**6) ICD Registry for Primary Prevention ICD Therapy**

HRS and ACC strongly support the need for Hospitals and providers to be certified as competent in ICD implantation and commends CMS for the inclusion of this criterion in the proposed registry. We urge that the recent guidelines developed by Heart Rhythm Society and endorsed by the ACC serve as the basis for this certification.

Although we both support the principle of requiring some type of registry, it will take a substantial effort to develop a database that will meet the objectives outlined by CMS. It is

frankly not possible to finalize the infrastructure and funding for the database by January 1, 2005. In addition to establishing a database, nonelectrophysiologists need time to meet the requirements for certification. Moreover, training programs and a certification process must be established to facilitate their compliance with the proposed Registry. It would not be acceptable to withhold primary prevention ICD therapy until the database is fully operational. At CMS' request, the Heart Rhythm Society has appointed representatives, including the Chair, to the National ICD Registry Working Group. Representatives from the ACC, AHA, Heart Failure Society of America, industry, and other groups with experience in data base management will also be participating. This Working Group will be asked to develop the database and a business model to sustain it as soon as feasible. We agree with CMS that reimbursement for primary prevention ICD therapy should be tied to participation in the Registry. It will be difficult to achieve compliance if the Registry is voluntary.

**HRS and ACC request a grace period while the registry is developed, funding is identified, and the infrastructure established for patient entry. The National ICD Registry Working Group will advise CMS about a reasonable time frame required to meet this objective. During that interval we recommend that CMS provide coverage for life-saving primary prevention ICD therapy.**

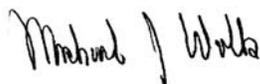
In summary, we appreciate the opportunity to work with CMS in refining the coverage decision and developing an ICD Registry that will meet the objectives outlined by CMS. We encourage CMS to stand by its requirement that ICDs should only be implanted by physicians with appropriate training for patient selection and implantation of these devices as outlined by the Heart Rhythm Society Clinical Competency Statement: Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices.

HRS and ACC look forward to working with you towards implementation of this critical coverage decision that will ultimately save many lives. If you have any questions, please contact Amy Melnick, Vice President, Health Policy, HRS, at [amelnick@HRSONline.org](mailto:amelnick@HRSONline.org), 202-327-5430 or Barbara Greenan, Senior Director, Advocacy, ACC, [bgreenan@acc.org](mailto:bgreenan@acc.org) or 301-897-2687. Thank you very much for your consideration of our comments.

Sincerely,



Stephen Hammill, MD  
President, Heart Rhythm Society



Michael J. Wolk, MD, FACC  
President, American College of Cardiology

Cc: Steve Phurrough, MD, MPA, CMS  
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