



# Heart Rhythm Society<sup>SM</sup>

September 14, 2007

VIA ELECTRONIC MAIL

Stuart Caplan RN, MAS  
Senior Analyst  
Centers for Medicare & Medicaid Services  
Office of Clinical Standards & Quality  
7500 Security Blvd  
Baltimore, MD 21224

Re: NCA Tracking Sheet for Microvolt T-wave Alternans (CAG-00293R)

Dear Mr. Caplan:

The Heart Rhythm Society (HRS) appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services' (CMS) reconsideration of the National Coverage Decision (NCD) on Microvolt T-wave Alternans (MTWA) to authorize coverage for measurement of MTWA using the modified moving average method.

In our previous comments on use of MTWA, HRS took the position that it was premature to recommend reimbursement for this method of analysis because we felt that additional randomized clinical trials were needed. While we agreed that MTWA is useful as a diagnostic tool for risk stratification of patients at risk for sudden cardiac death, HRS declined to support routine use of MTWA in selecting patients for an ICD until more data became available. Our position has not changed in that we support further investigation and refinement of this technology.

HRS has reviewed GE Healthcare's application for coverage of the modified moving average method to assess MTWA and concluded that there is insufficient evidence to accurately comment on the utility of this method of analysis as a method for selecting patients at risk for sudden cardiac death. This conclusion is consistent with our original position. We are aware that several clinical trials are in progress to assess the predictive value of MTWA. When additional data becomes available, we will be pleased to reassess our position at that time.

HRS appreciates this opportunity to offer our comments. If you have any specific questions regarding our recommendations, please contact Lisa Miller-Jones, Director of Reimbursement and Regulatory Affairs at (202) 464-3433 or at [lmiller-jones@HRSONline.org](mailto:lmiller-jones@HRSONline.org).

Sincerely,

Bruce D. Lindsay, MD, FHRS  
President, Heart Rhythm Society