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Dear Mr. Caplan:

This letter is a formal request for reconsideration of the National Coverage Determination (NCD) for Microvolt T-Wave Alternans (20.30). The current decision is written in such a way that it requires 1) a specific type of technology, 2) specific equipment, and 3) a specific protocol.

Since the decision was placed into effect, additional peer reviewed articles have been published by Nieminen et al in *European Heart Journal* (2007), as well by as others, who directly studied the time domain method of measuring T-wave Alternans known as Modified Moving Average (MMA). As you will see, the research has shown that there is substantial equivalence between the MMA and the spectral methods. We will also provide data that illustrates that even though both techniques are unique, they are essentially measuring the same phenomenon.

FDA has issued two pre-market notifications for T-wave Alternans Algorithm Option using the MMA method. The indicated use for the algorithm provides for the measurement performance with an accuracy and resolution of 1 microvolt and to be predictive of arrhythmic death and used for risk stratification (K023380 & K032513).

We request that CMS reconsider this decision and edit the language to allow reimbursement of the Modified Moving Average method of measuring T-Wave Alternans.

Regards,

A handwritten signature in black ink, appearing to read 'Jeffrey A. Conner'.

Jeffrey A. Conner RN, BSN
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