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Tamara Syrek-Jensen, J.D.
Acting Director, Coverage and Analysis Group,
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

March 20, 2014

Re: Formal request for reconsideration for national coverage determination (NCD) on Microvolt T-wave Alternans (MTWA) diagnostic testing to extend coverage to the Modified Moving Average (MMA) method

Dear Ms. Syrek-Jensen:

This is in follow-up to the letter sent on July 15, 2013 to Dr. Louis Jacques regarding our request for reconsideration for national coverage determination (NCD) on Microvolt T-wave Alternans (MTWA) diagnostic testing to extend coverage to the Modified Moving Average (MMA) method.

In accordance with the Federal Register published on 7-Aug-13 on the Process for Making National Coverage Determinations (see Vol. 78. No. 152), we would like to add the following clarifications that are required by the statute:

This is a formal request for NCD Reconsideration of CMS's most recent decision memo (CAG-00293R) on May 12, 2008, regarding CPT 93025: "Microvolt T-Wave Alternans Diagnostic Testing." The decision did not allow Medicare coverage of the Modified Moving Average (MMA) Method of T-wave alternans (TWA) analysis. The previous review did not evaluate the substantial comparability of MMA method with the reimbursed Spectral Method.

Specifically, we request consideration of the substantial comparability of Modified Moving Average (MMA) Method of T-wave alternans (TWA) analysis with the Spectral Method. The target Medicare population is: Medicare recipients under Part B "medically necessary services." The medical indications are: "for sudden cardiac death prediction and risk stratification." The device is intended for use by competent healthcare professionals.

The body of evidence pertinent to MMA is significantly more robust than when Medicare last considered this issue in 2008, as stated in the July 26, 2013, dossier, which reviews the substantial new clinical evidence from peer-reviewed journals supporting the clinical indications, relevance, usefulness, and medical benefits of MMA analysis. In addition, at the time of the previous review, the 2011 T-Wave Alternans Consensus Guideline (J Am Coll Cardiol 2011; 58:1309-1324) by 11 experts, sponsored by 3 professional societies, had not been published. That document underscored the substantial comparability of the Spectral and MMA methods:

- a. The [Spectral and MMA] methods are analytically comparable.... (page 1316).

- b. Hazard ratios for prediction by the Spectral and MMA methods are similar, whether in the same population or in studies overall (page 1319).
- c. Evidence supports the value of quantitative TWA analysis for both the Spectral and MMA methods (page 1321).

The MMA Method is a FDA cleared medical device: "The algorithm performs the measurement of this variation at an accuracy and resolution of 1 microvolt" and has "been found to be predictive of arrhythmic death and can be used for the purposes of risk stratification" (K032513).

Regards,

A handwritten signature in black ink, appearing to read "Scott K. Burke". The signature is fluid and cursive, with the first name "Scott" being the most prominent.

Scott K. Burke
Director, Ambulatory ECG