American Heart Association | American Stroke Association

February 22, 2013

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00063R3

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) national coverage analysis for single-chamber and dual-chamber permanent cardiac pacemakers.

CMS opened the coverage analysis after receiving a joint request from the Heart Rhythm Society (HRS) and the American College of Cardiology (ACC). The organizations have asked CMS to revise the coverage policy by updating the clinical indications for dual-chamber cardiac pacemakers. According to the HRS and ACC request, the organizations believe that the existing Medicare policy does not align with current clinical guidelines, and that an expansion and clarification of coverage for dual-chamber cardiac pacemakers is warranted.

AHA supports the HRS/ACC request. We agree that the coverage policy should be updated and we recommend that CMS adopt the revised clinical indications submitted by HRS and ACC. The proposed clinical indications align closely with the HRS/ACCF Expert Consensus Statement on Pacemaker Device and Mode Selection. They are also consistent with the 2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. By incorporating the HRS/ACC recommendations, the coverage policy would now reflect the clinical practice recommendations that guide health care professionals in the treatment of their patients.

In addition to offering our support for the HRS/ACC revised clinical indications, AHA would like to suggest a few minor refinements to the text.

Change “with/without” in clinical indication number three to “with or without” so that it reads:

> Patients with intrinsic sinus node dysfunction <u>with or without</u> coexistent tachyarrhythmias or AV conduction block or iatrogenically-mediated sinus node dysfunction as the consequence of necessary pharmacologic treatment

> for which there is no acceptable alternative treatment when accompanied by significant symptoms (e.g. shortness of breath, dyspnea on exertion, pre-syncope or syncope, seizures, congestive heart failure, dizziness or confusion).

Change "bifascicular/trifascicular" in clinical indication number six to "bifascicular or trifascicular" so that it reads:

> Patients with high grade AV block including, but not limited to: Complete third degree AV block, second degree type II AV block, symptomatic second degree type I AV block or symptomatic first degree AV block. Additionally, select patients with bifascicular or trifascicular block accompanied by one of the following: 1) Syncope after other plausible causes such as ventricular tachycardia have been excluded, or 2) Finding of resting HV interval greater than or equal to 100 msec during electrophysiology study, or 3) Finding of pacing-induced infra-His block during electrophysiology study.

In clinical indication six, add the word "selected" so that it reads:

> Selected symptomatic or high-risk patients with congenital long QT syndrome.

In clinical indication seven, change the word "select" to "selected" so that it reads:

> Selected patients with medically refractory, symptomatic hypertrophic cardiomyopathy with significant or provoked left ventricular outflow obstruction. (e.g. symptoms including shortness of breath, chest pain, dyspnea on exertion, lightheadedness, orthopnea, paroxysmal nocturnal dyspnea, pre-syncope or syncope, etc.)

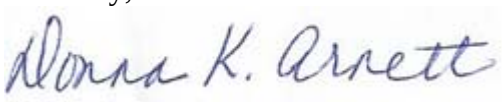
Also, while the clinical indications for single-chamber pacemakers are not addressed in the HRS/ACC request, AHA has reviewed that section of the coverage policy as well and we recommend that CMS make the following change. In noncovered indication four, change "P-R intervals" to "R-R intervals" so that it reads:

> Prolonged R-R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.

In closing, we reiterate our support for the revisions proposed by HRS and ACC and we encourage CMS to update the clinical indications for dual-chamber pacemakers. The recommended changes are a more accurate reflection of current clinical practice.

Thank you for consideration of our comments. If you have any questions or require any additional information, please contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Sincerely,



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