



AMERICAN  
COLLEGE of  
CARDIOLOGY



December 13, 2016

Ms. Tamara Syrek-Jensen  
Director, Coverage & Analysis Group  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Draft National Coverage Decision (NCD) for Leadless Pacemakers (CAG-00448N)

Dear Ms. Syrek-Jenson:

The American College of Cardiology (ACC), Heart Rhythm Society (HRS), and Society for Cardiovascular Angiography and Interventions (SCAI) are the non-profit professional associations representing the majority of practicing electrophysiologists and interventional cardiologists in the United States. These members have expertise in the diagnosis and treatment of patients with heart rhythm disorders and structural heart disease. ACC, HRS and SCAI appreciate the opportunity to submit joint comments on the NCA for leadless pacemakers. This letter represents the consensus of the three societies.

The Centers for Medicare & Medicaid Services (CMS) proposes to cover FDA-approved studies for leadless pacemakers through Coverage with Evidence Development (CED). The Societies interpret this proposal to mean that no allowance will be made for coverage of patients who meet FDA approved indications but do not have access to participate in an FDA approved clinical trial (or FDA approved post-market approval study). This restriction will present a significant obstacle to patients' access to this unique and important new therapy. **The Societies strongly encourage CMS to modify its proposal and, instead, cover FDA-approved leadless pacemaker devices for Medicare beneficiaries who meet FDA-approved indications.** The Societies recognize that significant questions regarding leadless pacemaker technology remain and strongly support collection of the necessary data to address critical clinical questions. The final coverage policy should provide appropriate patients access to this important new technology in conjunction with a robust mechanism of data collection to answer outstanding questions.

As outlined in our June 16, 2016 comment letter (attached), leadless pacing offers important advantages over transvenous pacemaker technology by eliminating the components most prone to short and long-term complications: the pacemaker leads and pocket. Lead failure and pocket infections are two of the most common and serious causes of morbidity amongst the Medicare patient population with traditional pacemaker systems. Among patients with vascular access limitations, epicardial pacing (a surgical approach associated with significant morbidity and poor long-term pacing outcomes often requiring repeat surgical procedures) would be the only alternative. Prospective evaluation of leadless pacing has demonstrated the technology to be safe and effective compared with transvenous historical controls, with 99.2% of the enrolled 725 patients receiving a successful implant and 96% reaching the primary safety endpoint.<sup>i</sup>

As with other new technologies, knowledge gaps remain. Specifically, how will the technology perform in the long term, how will patients be managed once the battery is depleted, will there be low-frequency, late complications, and how will the acute safety and effectiveness of the device compare with transvenous pacing outside of the clinical trials? Answering these questions will improve patient care as more is learned about leadless pacemaker technology in the long term. However, in the short term, a technology exists that the FDA has deemed to be safe and effective to treat patients with (1) symptomatic paroxysmal or permanent high-grade AV block in the presence of AF, (2) symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy, or (3) symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy.

Physicians and patients should be able to thoroughly consider all available therapies that are appropriate, discuss the known risks and benefits at the current life cycle of the technology, and then make a documented decision on how to proceed. **We encourage CMS and the vendor community to work together with societies to develop a robust and minimally burdensome mechanism to capture data needed to answer these questions without restricting access to this important new technology.**

Thank you for your consideration. The Societies are committed to accelerating access to safe, effective, reasonable, necessary and innovative technology. If you have questions or need additional information regarding any of these comments, please contact James Vavricek at [jvavricek@acc.org](mailto:jvavricek@acc.org), Kim Moore at [kmoore@hrsonline.org](mailto:kmoore@hrsonline.org), or Dawn Gray at [dhopkins@scai.org](mailto:dhopkins@scai.org).

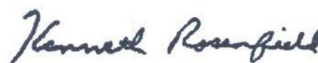
Sincerely,



Richard A. Chazal, MD, FACC  
ACC President



Michael R. Gold, MD, FHRS  
HRS President



Kenneth Rosenfield, MD, MSCAI  
SCAI President

Attachment

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<sup>i</sup> Reynolds D, et. al. New Eng J Med 2016;374:533-41.