



Louis Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
S3-02-01
Baltimore, MD 21244

RE: A Formal Request for a NCD Reconsideration of Cardiac Pacemakers (NCD 20.8)

December 18, 2012

Dear Dr. Jacques:

Please accept this letter as a formal request for reconsideration of the National Coverage Determination (NCD) for Cardiac Pacemakers (NCD 20.8). We appreciate the Centers for Medicare and Medicaid Services' (CMS) receptiveness to the Heart Rhythm Society and the American College of Cardiology's request to update the clinical indications for dual-chamber pacemaker implantation. Our request for revisions focus on the clinical indications for dual-chamber pacemakers: Group II: Dual-Chamber Cardiac Pacemakers. We do not recommend additional modifications to the NCD.

Item/Service Description

Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart.

Item/Service Use

Cardiac pacemakers are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block and symptomatic sinus bradycardia.

Benefit Category

The NCD affects benefit categories: Inpatient Hospital Services, Physician Services, and Prosthetic Devices, though this may not be an exhaustive list of all applicable benefit categories for this item or service.

Medical/Scientific Information

In the recent past, the paucity of clinical guidance on pacemaker device and mode selection created an obstacle to revising the NCD for Cardiac Pacemakers to align with current clinical practice. We assert that the misalignment between the Medicare coverage policy and the current clinical guidelines has led to Medicare denials for dual-chamber pacemaker implantation.

On July 30, 2012, the Heart Rhythm Society (HRS)-American College of Cardiology Foundation (ACCF) promulgated *the HRS/ACCF Expert Consensus Statement on Pacemaker Device and Mode Selection*. (Attachment A) This expert consensus statement and its supporting information were prepared in response to HRS and ACC's meeting with the CMS Coverage and Analysis Group staff in August 2011 and a conference call in May 2012. Published in the August 2012 edition of *Heart Rhythm*, the statement provides a state of the art review of the field and reports the recommendations of a consensus writing group. The document focuses on pacemaker device and mode selection in the adult patient. The recommendations summarize the opinions of the expert writing group, based on an extensive literature review as well as their own clinical experience. Our view is that the consensus statement and supporting evidence endorse an expansion and clarification of coverage for the use of dual-chamber pacemakers. In July 2012, HRS and ACC submitted supporting information via a CD to the CMS Coverage and Analysis Group staff. That CD includes:

1. Supporting Data Table of Contents (PDF);
2. HRS/ACCF Pacemaker Expert Consensus Statement on Pacemaker Device and Mode Selection (PDF);
3. Literature Abstracts from Expert Consensus Statement (PDF);
4. Expert Consensus Reference Articles (Subfolder);
5. Literature Abstracts from Environmental Scan (PDF); and
6. Environmental Scan Reference Articles (Subfolder).

As CMS received the supporting documentation in that July 2012 correspondence, this formal request for reconsideration includes the expert consensus statement and proposed revisions to the Group II indications. We will provide additional copies of the literature review and articles per request.

On September 25, 2012 HRS and ACC staff met with CMS Coverage and Analysis Group Staff to determine the next steps to request the reconsideration of the NCD. Subsequent to the September meeting, HRS's Subcommittee on Reimbursement and Regulatory Affairs (physicians and professional coders); the co-chairs of the HRS/ACCF consensus writing group and the current and immediate past presidents of HRS compared the existing coverage with Table I of the expert consensus statement. With the support of these medical experts and their analysis of the clinical and scientific evidence, HRS and ACC are submitting revisions to the existing NCD. These revisions include new indications as well as modifications to existing indications for Group II: Dual-Chamber Cardiac Pacemakers. These recommendations provide specificity for the clinical indications and link the clinical evidence for the indications to the relevant, supporting literature. (Attachment B) In addition to updating the indications to reflect

current clinical practice, we removed ambiguity from the current indications. We hope that you and your staff find our approach valuable and effective.

We look forward to our ongoing collaboration with you throughout this process. If you need additional information, please contact HRS's Director of Reimbursement and Regulatory Affairs, Kimberley Moore at KMoore@hrsonline.org.

Sincerely,



Bruce L. Wilkoff, MD, FHRS
Immediate Past President
Heart Rhythm Society



William A. Zoghbi, M.D., F.A.C.C.
President
American College of Cardiology

Attachments:

- A: HRS/ACCF Expert Consensus Statement on Pacemaker Device and Mode Selection
- B: Proposed revisions to Group II: Dual-Chamber Cardiac Pacemakers

cc: Laura Blum
Rebecca Kelly
Kimberley Moore
Jyme Schaefer
James Vavricek