June 28, 2013

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

RE: Proposed Decision Memo for Cardiac Pacemakers Single-Chamber and Dual-Chamber Permanent Cardiac Pacemakers (CAG-00063R3)

Dear Dr. Jacques:

The Heart Rhythm Society (HRS) and the American College of Cardiology (ACC) appreciate this opportunity to comment on the proposed decision memo. The societies have been working together with member experts and CMS staff for some time to find the correct way to update this national coverage decision (NCD) in a manner that accounts for advances in technology and current standards of clinical practice.

While we requested modest changes only to the covered indications for dual-chamber pacemakers—a particular area of concern for our members—we view the proposed decision as a significant improvement over the existing coverage indications. Removing the distinctions for covered indications of single- and dual-chamber pacemaker implantation simplifies the coverage structure, removes some ambiguity from existing indications, and provides a degree of certainty to cardiologists who make the decision to employ these therapeutic devices. **We support covering both single- and dual-chamber implanted permanent cardiac pacemakers for the identical indications of documented symptomatic bradycardia due to sinus node dysfunction, second-degree atrioventricular (AV) block, and third-degree AV block.**

Bradycardia caused by these three indications is not the only instances where implanted permanent pacing is appropriate. Our review of the indications proposed for non-coverage did raise some concerns. Our comparison of the existing coverage to both the new coverage and our requested coverage identified several previously covered indications that are now proposed for non-coverage. We also determined that several indications for which we expressly requested coverage are not addressed. We will focus our comments on those indications as well as several others for which we believe the proposed coverage fails to adequately address the needs of the patients and incorporate the evidence supporting current clinical practices.
Hypersensitive Carotid Sinus Syndrome
A patient with intermittent asystolic episodes caused by hypersensitive carotid sinus syndrome can benefit greatly from a pacemaker if these episodes are associated with substantial symptoms. Current guidelines offer appropriate direction for when pacing is appropriate. **We recommend the specific example of hypersensitive carotid sinus syndrome be removed from non-covered indication #14 regarding pacing that takes place intermittently.** This recommendation is based on the bulleted guideline recommendations below.

Hypersensitive carotid sinus syndrome with syncope due to bradycardia is currently covered under single-chamber indications. We are unaware of evidence to indicate this condition no longer warrants treatment. **As such, we also recommend the existing single-chamber indication #11 for these patients be included as a covered indication.**

- Permanent pacing is indicated for recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds. (Class I Recommendation, Level of Evidence C) (142, 152)
- Permanent pacing is reasonable for syncope without clear, provocative events and with a hypersensitive cardioinhibitory response of 3 seconds or longer. (Class IIa Recommendation, Level of Evidence C) (142)

Pacing After Acute Myocardial Infarction (AMI) (Temporary Complete and/or Mobitz Type II)
Certain patients who suffer AMI with AV block have unfavorable short- and long-term prognoses. Current guidelines offer appropriate direction for when pacing is appropriate. CMS currently covers single-chamber pacing after AMI for patients with certain characteristics. We are unaware of evidence to indicate this condition no longer warrants treatment. **As such, we recommend non-covered indication #7 be removed and the existing single-chamber indication #13 for these patients be included as a covered indication.** This edit aligns with the below guideline recommendations.

- Permanent ventricular pacing is indicated for persistent second-degree AV block in the His-Purkinje system with alternating bundle-branch block or third-degree AV block within or below the His-Purkinje system after ST-segment elevation MI. (Class I Recommendation, Level of Evidence B) (79, 126-129, 131)
- Permanent ventricular pacing is indicated for transient advanced second- or third-degree infranodal AV block and associated bundle-branch block. If the site of block is uncertain, an electrophysiological study may be necessary. (Class I Recommendation, Level of Evidence B) (126, 127)

Asymptomatic Second- and Third-Degree AV Block
The proposal identifies a number of asymptomatic indications for non-coverage. None of those are specific to third-degree AV block. Asymptomatic second- or third-degree AV block is a condition for which guidelines recommend pacemaker implantation in several situations. Some patients with these conditions will present with symptoms, but others will not. Coverage of asymptomatic heart block should be available for these patients. **We recommend a covered indication be added for documented advanced second-degree or third-degree block not due to a reversible cause even in the absence of symptoms, as well as second-degree block**
at an intra or infra HIS level documented on EP testing with or without symptoms. This edit aligns with the below guideline recommendations.

- Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients in sinus rhythm, with documented periods of asystole greater than or equal to 3.0 seconds (86) or any escape rate less than 40 bpm, or with an escape rhythm that is below the AV node. (Class I Recommendation, Level of Evidence C) (53, 58)

- Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients with AF and bradycardia with 1 or more pauses of at least 5 seconds or longer. (Class I Recommendation, Level of Evidence C)

- Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level after catheter ablation of the AV junction. (Class I Recommendation, Level of Evidence C) (87, 88)

- Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with postoperative AV block that is not expected to resolve after cardiac surgery. (Class I Recommendation, Level of Evidence C) (84, 85, 89, 90)

- Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy, with or without symptoms. (Class I Recommendation, Level of Evidence B) (91-97)

- Permanent pacemaker implantation is indicated for asymptomatic persistent third-degree AV block at any anatomic site with average awake ventricular rates of 40 bpm or faster if cardiomegaly or LV dysfunction is present or if the site of block is below the AV node. (Class I Recommendation, Level of Evidence B) (76, 78)

- Permanent pacemaker implantation is indicated for second- or third-degree AV block during exercise in the absence of myocardial ischemia. (Class I Recommendation, Level of Evidence C) (81, 82)

- Permanent pacemaker implantation is reasonable for persistent third-degree AV block with an escape rate greater than 40 bpm in asymptomatic adult patients without cardiomegaly. (Class IIa Recommendation, Level of Evidence C) (59, 63, 64, 76, 82, 85)

- Permanent pacemaker implantation is reasonable for asymptomatic second-degree AV block at intra- or infra-His levels found at electrophysiological study. (Class IIa Recommendation, Level of Evidence B) (74, 76, 78)

**Pacing to Prevent Tachycardia**

Our request for reconsideration included an indication for certain patients with long QT syndrome. That condition is not addressed as part of the proposed coverage. **We recommend a covered indication be added for symptomatic or high-risk patients with congenital long QT syndrome.** It is supported by our previous submission and the below guideline recommendations.

- Permanent pacing is indicated for sustained pause-dependent VT, with or without QT prolongation. (Class I Recommendation, Level of Evidence C) (188, 189)
• Permanent pacing is reasonable for high-risk patients with congenital long-QT syndrome. (Class IIa Recommendation, Level of Evidence C) (188, 189)

**Chronotropic Incompetence**

Our request for reconsideration included an indication for select patients with symptomatic chronotropic incompetence. That condition is not addressed as part of the proposed coverage. **We recommend a covered indication be added for select patients with symptomatic chronotropic incompetence.** This recommendation is based on our previous submission and the bulleted guideline recommendation below.

- Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence. (Class I recommendation, Level of Evidence C) (53-57)
- After heart transplant permanent pacing is indicated for persistent inappropriate or symptomatic sinus bradycardia not expected to resolve and for other Class I indications for permanent pacing. (Class I, Level of Evidence C)

**Hypertrophic Cardiomyopathy**

Our request for reconsideration included an indication for select patients with symptomatic hypertrophic cardiomyopathy. That condition is not addressed as part of the proposed coverage. **We recommend a covered indication be added for select patients with medically refractory, symptomatic hypertrophic cardiomyopathy with significant or provoked left ventricular outflow obstruction.** This recommendation is based on our previous submission and the bulleted guideline recommendation below.

- Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction. (Class IIa Recommendation, Level of Evidence: A) (233, 235, 237, 238, 246, 247)

**Reversible Bradycardia**

We generally agree with noncovered indication #1. However, this noncovered indication could be construed to include *essential* drug therapy that causes bradycardia. The below guideline offers a solution for this indication.

- Permanent pacemaker implantation is indicated for symptomatic sinus bradycardia that results from required drug therapy for medical conditions. (Class I Recommendation, Level of Evidence C)

This scenario is currently covered under single-chamber indication #7. **We request that indication #7 be carried forward into the updated coverage.**

**Intermittent Bradycardia**

We are concerned that noncovered indication # 14 stating that pacing is not indicated when it is needed only intermittently and briefly could be misconstrued by payers or auditors. Patients with intermittent asystolic episodes still can benefit tremendously from the pacemaker if these episodes are associated with substantial symptoms (such as syncope). Unexplained but profound episodic asystole due to sinus arrest is one example. A patient may only need a pacemaker once in several months, but if there is documented sinus arrest not due to a reversible cause, and not due to an explainable and correctable cause, a pacemaker can have a substantial impact on eliminating syncope and other symptoms due to this problem. Such use is brief and intermittent in
one sense, but would continue as these patients have a reasonable likelihood of needing pacing briefly and intermittently over a long period of time. **We recommend the indication be revised to say, “A clinical condition in which pacing takes place only intermittently and briefly, except for indications that require brief and intermittent pacing over a prolonged period of time, e.g, episodic asystole due to sinus arrest.”**

**Contractor Coverage**
In the event you do not find these recommendations adequate to revise the NCD covering these specific indications, we suggest that it would be appropriate to leave coverage of hypersensitive carotid sinus syndrome, pacing after AMI, asymptomatic second- and third-degree AV block, prevention of tachycardia, chronotropic incompetence, and/or hypertrophic cardiomyopathy for contractors to determine.

Thank you for your careful consideration of these comments and your continued work on this complex issue. We believe incorporation of these revisions will allow greater harmonization between current clinical guidelines on pacing and coverage. We are including the guideline and a bibliography of the literature supporting the guideline recommendations for your review. Please contact James Vavricek, Senior Specialist in Regulatory Affairs for ACC, at jvavricek@acc.org or Kim Moore, Director of Reimbursement and Regulatory Affairs for HRS, at kmoore@hrsonline.org if you have questions or need additional information.

Sincerely,

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Enclosures
Bibliography


