



**Heart
Rhythm
Society**SM



**AMERICAN
COLLEGE *of*
CARDIOLOGY**

June 29, 2017

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

RE: National Coverage Analysis (NCA) for Implantable Cardioverter Defibrillators (CAG-00157R4)

Dear Ms. Syrek-Jensen:

The Heart Rhythm Society (HRS) and the American College of Cardiology (ACC) are the non-profit professional associations representing the majority of practicing electrophysiologists in the United States. These members have expertise in the diagnosis and treatment of patients with heart rhythm disorders. The discipline of electrophysiology has undergone significant change in recent years, crossing clinical frontiers in the treatment of sudden cardiac death. As these advancements occur, HRS and ACC remain committed to improving the quality, and safety of evidence-based patient care.

HRS and ACC appreciate the opportunity to submit joint comments on the Centers for Medicare and Medicaid Services' (CMS) request for comment on this national coverage analysis to reconsider coverage indications in the national coverage determination (NCD) for implantable cardioverter defibrillators (CAG-00157R4). This comment letter represents the two societies' consensus on recommendations to the Agency to update the clinical indications for reimbursement in a manner that reflects current, evidence-based medicine.

The Societies recommendations for proposed modifications to the current indications for coverage are included as an attachment along with a spreadsheet that demonstrates areas of misalignment between the current national coverage determination and the existing evidence base. Citations are included with the spreadsheet (Attachment B) supporting the Societies' identification of misalignment between the 2005 coverage determination and the current clinical evidence. Per the Agency's instructions, the referenced attachments were sent to CAGinquiries@cms.hhs.gov.

Background

The implantable cardioverter defibrillator (ICD) is an important treatment option for selected patients who are at risk of sudden cardiac death. Randomized trials have consistently shown that ICD implantation reduces mortality in patients with heart failure and reduced left ventricular function, as well as in patients who have suffered a life threatening ventricular arrhythmia.

Under the current national coverage determination, there is a lack of harmony between the randomized trial evidence, clinical guidelines and the Medicare coverage policy as it was written in 2005. Evidence demonstrates that Medicare beneficiaries have outcomes concordant with those observed in the randomized trials. Nevertheless, questions remain. The Societies support voluntary data collection and clinical trials to address outstanding questions. The Societies also endorse voluntary reporting for quality improvement and performance measurement.

Current Clinical Guidance and Recommendations

The nuanced decision-making necessary for the best use of ICD therapy was recognized by the professional societies, and the *HRS/ACCF/AHA Expert Consensus Statement on the Use of Implantable Cardioverter Defibrillator Therapy in Patients Who are Not Included or Well Represented in Clinical Trials* was developed to help clinicians manage “real world” patients with multiple medical problems. For example, patients with left ventricular dysfunction in the setting of a recent myocardial infarction or recent coronary artery revascularization should be considered for ICD therapy if they have symptomatic bradycardia, syncope, sustained ventricular arrhythmias, or previously documented severe left ventricular dysfunction. It is clear that the complexities of medicine require flexibility to provide individualized patient care.

The 2017 ACC/AHA/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death is expected to be released in October 2017. The overarching goal of this document is to provide an up-to-date guideline for treating adults with ventricular arrhythmias and/or who are at risk for sudden cardiac death. This guideline will include indications for ICDs for the treatment of VA and prevention of sudden cardiac death, and it will update some recommendations from earlier guidelines in light of new evidence or improved understanding of existing evidence. The Societies will provide it to the Agency as soon as the document development process allows.

Technological Advances

Advances in technology over the next ten to fifteen years are likely to change therapy options for patients at risk of sudden cardiac death in ways that are difficult to predict or imagine. The leadless pacemaker and subcutaneous ICD are two recent examples of transformative technology that were not explicitly addressed in the existing ICD or pacemaker NCDs, but that offer clear advantages over older technology for appropriately identified patients. We urge

CMS to create a policy that gives patients access to important new therapies that have demonstrated safety and effectiveness in randomized clinical trials and that have received FDA approval.

Patient Populations

The evidence supports coverage of ICDs for Medicare beneficiaries falling into two broad categories:

- 1) Patients who have suffered a cardiac arrest due to ventricular arrhythmia (VA) or have demonstrated an episode of sustained VT outside the setting of a reversible cause.
- 2) Patients at high risk for life-threatening VA including those with an inherited or familial condition or heart failure due to ischemic or nonischemic causes with significantly reduced ejection fraction on optimal medical therapy who are ambulatory.

The Societies recognize that practical considerations make the application of this technology more or less appropriate in a given circumstance. HRS and ACC agree that waiting periods to evaluate the effect of guideline directed optimal medical therapy are appropriate and necessary. However, in certain scenarios, these are not feasible or appropriate. For example, some patients develop life-threatening slow abnormal heart rhythms during the waiting period. If a patient received a pacemaker and then at the end of the waiting period was determined to need an ICD that patient would be subjected to two surgical procedures. The risk of infection from opening up the surgical pocket, removing the pacemaker and lead and then implanting an ICD and defibrillator lead would be associated with significant risk and morbidity for the patient. Similarly, some patients will have existing ICDs or pacemakers that reach battery voltage depletion or malfunction during the waiting period. These patients cannot wait to receive a new device. For all patients with any indication, physicians and patients engage in thorough consent and decision making discussions, considering risks and benefits of ICD therapy.

HRS and ACC believe that the additional clinical data gathered since 2005 regarding primary prevention ICDs for ischemic and nonischemic cardiomyopathy patients reaffirm CMS's decision to provide coverage for these patient populations. While not all trials confirmed a mortality benefit, such as the DANISH trial, the overwhelming weight of the evidence favors primary prevention in these groups. (Please see the subfolder in the Dropbox titled "Primary Prevention ICD in non-ischemics" for research and publications on this topic.)

Attachment A provides additional details regarding the Societies' recommended changes to coverage to better align with the evidence listed in Attachment B and includes a restructured and condensed proposal. The key differences between the 2005 NCD and the restructured version are the following:

- Patients with LVEF $\leq 40\%$ demonstrating non-sustained ventricular arrhythmias at least 4 days post-MI or coronary revascularization procedure who have inducible sustained VT or VF at electrophysiological testing

- Inclusion of patients with Class IV heart failure who are awaiting heart transplant
- Exceptions to the 40 day and 3 month waiting period for patients with existing ICDs or pacemakers that require surgical revision for reasons such as battery depletion or device malfunction, patients with sustained VT, and patients with syncope thought to be due to VT or VF
- Inclusion of MRI as an acceptable modality for assessing left ventricular function (in addition to echo, angiography or radionuclide scanning)

Data Collection

CMS's 2005 coverage decision for ICDs mandated hospital participation in a national registry to address areas of uncertainty regarding the use and effectiveness of ICDs in routine clinical practice. In doing so, CMS supported the expansion of the evidence base for ICDs. Since 2006, the ICD Registry has served as the sole approved registry for hospitals implanting primary prevention ICDs in patients with Medicare insurance coverage. Nearly all hospitals that implant ICDs currently participate in the ICD Registry and have used information from the ICD Registry for purposes of quality improvement. Data generated in the ICD Registry have been employed to address many of the questions laid out in the CED as well as questions around clinical outcomes in real-world populations, optimal device selection, post-market safety surveillance, and care equity. As such, we recommend that CMS reevaluate the CED requirement for study or registry participation as a condition of coverage.

We appreciate the Agency's action to reconsider coverage indications for implantable cardioverter defibrillators. If you have questions about the Societies' recommendations, please contact Laura Blum at lblum@hrsonline.org or James Vavricek at jvavricek@acc.org. We look forward to working with you throughout the coverage determination process.

Sincerely,



George F. Van Hare, MD, FHRS, CCDS, CEPS-PC
President, Heart Rhythm Society



Mary Norine Walsh, MD, FACC
President, American College of Cardiology

Attachment A: Recommended changes to the NCD's indications and limitations of coverage

Attachment B: Spreadsheet of clinical evidence

Attachment C: Literature Dropbox

Benefit Category

Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening ventricular tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.

Indications and Limitations of Coverage

B. Secondary prevention covered indications:

1. Documented episode of cardiac arrest due to ventricular tachycardia (VT) or fibrillation (VF), not due to a transient or reversible cause.

C. Primary prevention covered indications:

1. Ischemic cardiomyopathy:
 - a. Patients with prior MI and LVEF $\leq 35\%$, New York Heart Association Class (NYHA) II or III.
 - b. Patients with prior MI and LVEF $< 30\%$ with NYHA I
2. Non-ischemic cardiomyopathy:
 - a. Patients with LVEF $\leq 35\%$ and NYHA II or III.
3. Documented familial, inherited or acquired conditions with a high risk of life-threatening VT or VF, such as long QT syndrome or hypertrophic cardiomyopathy.
4. Bridge to transplant:
 - a. Patients deemed eligible for heart transplant with NYHA IV heart failure regardless of etiology of myopathy.

D. Waiting periods:

1. Ischemic cardiomyopathy:
 - a. ≥ 40 days after MI
 - b. ≥ 3 months after revascularization

2. Non-ischemic dilated cardiomyopathy:
 - a. ≥ 3 months following initiation of guideline-directed optimal medical therapy

E. Exceptions to primary prevention waiting periods:

1. Patients who meet criteria for pacemaker implantation (per CMS NCD)
2. Patients with sustained VT
3. Patients who present with syncope thought to be due to VT or VF
4. Patients with an existing ICD or pacemaker that requires replacement for reasons such as battery voltage depletion or device malfunction.
5. Patients with LVEF $\leq 40\%$ demonstrating non-sustained ventricular arrhythmias at least 4 days post-MI or coronary revascularization procedure who have inducible sustained VT or VF at electrophysiological testing

F. Cardiac resynchronization therapy:

1. Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure.

G. Additional exclusion criteria:

1. Any co-morbid disease associated with a likelihood of survival less than 1 year.
2. Clinical symptoms or findings of coronary ischemia amenable to revascularization
3. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm
4. Irreversible brain damage from preexisting cerebral disease.

H. Patients enrolled in clinical trial:

1. All other indications for implantable automatic defibrillators not currently covered in accordance with this decision will continue to be covered under Category B IDE trials (42 CFR §405.201) and the CMS routine clinical trials policy (NCD §310.1).

I. Definitions:

1. Qualifying measurement of LV EF may be obtained by angiography, radionuclide scanning, MRI or echocardiogram.