

## National Coverage Determination for Implantable Cardioverter Defibrillators (CAG-00157R4)

### Key Aspects

**Effective Date:** February 15, 2018.

The changes are effective immediately, though contractors must wait for further technical instructions from CMS before updating claims processing software.

The full decision memo is available on the HRS website at <https://www.hrsonline.org/Policy-Payment/Updated-ICD-Coverage-Policy-2018>.

The Heart Rhythm Society and the American College of Cardiology developed a 20 min complimentary webinar, which provides an overview of the update policy and the requirement of a shared decision making. The webinar is available at <https://www.hrsonline.org/Policy-Payment/Webinar-2018-ICD-Coverage-Policy>

### Covered Indications

**1. Patients with a personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation. Patients must have demonstrated:**

- An episode of sustained ventricular tachyarrhythmia, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction and not due to a transient or reversible cause; or
- An episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause.

**2. Patients with a prior myocardial infarction and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:**

- New York Heart Association (NYHA) classification IV heart failure;
- Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
- Had a myocardial infarction within the past 40 days; or
- Clinical symptoms and findings that would make them a candidate for coronary revascularization.

**A formal shared decision making encounter is required.**

**3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%. Additionally, patients must not have:**

- Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
- Had a myocardial infarction within the past 40 days; or
- Clinical symptoms and findings that would make them a candidate for coronary revascularization.



**A formal shared decision making encounter is required.**

4. **Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF)  $\leq$  35%, been on optimal medical therapy (OMT) for at least 3 months. Additionally, patients must not have:**
- Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
  - Had a myocardial infarction within the past 40 days; or
  - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

**A formal shared decision making encounter is required.**

5. **Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained ventricular tachycardia or ventricular fibrillation), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.**

**A formal shared decision making encounter is required.**

6. **Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.**

For each of these groups listed above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. Left ventricular ejection fraction (LVEF) must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:
  - Significant, irreversible brain damage; or
  - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or
  - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

## **Requirement for Shared Decision Making Encounter**

The policy institutes a requirement for shared decision making for the covered indications B2-B5. CMS defines it as:

“a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based

decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.”

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### **Exceptions to Waiting Period**

Exceptions to waiting periods for patients that have had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months, or had a myocardial infarction within the past 40 days:

**Cardiac Pacemakers:** Patients who meet all CMS coverage requirements for cardiac pacemakers and who meet the criteria in this national coverage determination for an ICD may receive the combined device in one procedure at the time the pacemaker is clinically indicated;

**Replacement of ICDs:** Patients with an existing ICD may receive a ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

### **End of the Registry Requirement**

Participation in a data collection registry is no longer required. However, voluntary registry participation can continue to create value for future patients, clinicians, and facilities as a mechanism of quality improvement, safety, and appropriate use verification.