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 ≤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≤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 ≤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.