Implantable Automatic Cardiac Defibrillators (ICDs)

Origination: February 23, 2005
Review Date: May 13, 2009
Next Review: June 2011

DESCRIPTION OF PROCEDURE OR SERVICE
The implantable automatic cardiac defibrillator (ICD) is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The ICD can prevent sudden cardiac deaths by shocking an abnormal heart back into rhythm. The device consists of a pulse generator and electrodes for sensing arrhythmias and defibrillating the heart when necessary.

POLICY STATEMENT
Coverage will be provided for implantable automatic ICD’s when it is determined to be medically necessary when the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION
Please refer to the member’s individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:
- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

CRITERIA REQUIRED FOR COVERAGE APPROVAL
Documentation of any of the following:
1. An episode of cardiac arrest due to ventricular fibrillation (VF) not due to a transient or reversible cause; or
2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause; or

3. Participation in Category B investigational device exemptions (IDE) (See Special Notes) clinical trials (requires documentation from the physician) or other trials covered under CMS Clinical Trials policy (see Medical Coverage Policy on Clinical Trial Services); or

4. Ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI) (as documented by elevated cardiac enzymes or Q-waves on an electrocardiogram), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) < 35%; or

5. Nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤35%; or

6. Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device (See Special Notes) and have NYHA Class IV heart failure; or

7. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy; or

8. Coronary artery disease with a documented MI that has occurred more than 4 weeks prior to defibrillator insertion, a measured left ventricular ejection fraction (EF) ≤35%, and inducible, sustained VT or VF at EP study performed more than 4 weeks after the qualifying MI; or

9. Documented prior MI and a measured LVEF ≤30%.

**WHEN COVERAGE WILL NOT BE APPROVED**

1. New York Heart Association classification IV, unless criteria is met as indicated in bullet # 6 above;

2. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;

3. History of coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past three (3) months;

4. An enzyme-positive MI within the past 40 days;
5. Clinical symptoms or findings that would indicate the member is a candidate for coronary revascularization;

6. Any disease, other than cardiac disease (e.g., cancer, liver failure), associated with a likelihood of survival less than one (1) year; or

7. Irreversible brain damage, disease or dysfunction that precludes the ability to give informed consent.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: 33240, 33241, 33243, 33244, 33245, 33246, 33249

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

- Patients at low risk for sudden cardiac death do not benefit from an implantable automatic cardiac defibrillator, according to the Multicenter Automatic Defibrillator Implantation Trial II.

- Category B device defined as: a device for which the incremental risk is the primary risk in question (that is, the underlying questions of safety and effectiveness of the device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

- Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.

- Criteria for CRT include: patient is symptomatic despite optimal medical therapy with ACE inhibitors & beta blockers as well as other appropriate pharmacological measures; symptoms of moderate to severe congestive heart failure (NYHA Class III or IV); LVEF <35% and the QRS duration is >130ms. All provisions must be met and documented. Although patients with a Left Ventricular End Diastolic Diameter (LVEDD) of 55mm or greater are the group for which data suggests optimum clinical improvement, this will not be used as an exclusionary criterion when all the other requirements have been satisfied.
• The Centers for Medicare & Medicaid (CMS) has established a national registry for ICD’s to ensure that defibrillator implantation only occurs in those patients who are most likely to benefit. Care Management & Operations-Medicare C/D staff will confirm with the provider that the patient has been included in this registry or will suggest they are included.

References:

Policy Implementation/Update Information:
Revision Date:
November 30, 2006: No criteria changes made.
June 17, 2009: New online format; no criteria changes made.

Approval Dates:
Medical Coverage Policy Committee: May 5, 2009
Physician Advisory Group Committee: May 13, 2009
Quality Improvement Committee: June 17, 2009

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