

Policy #: 070

Original policy date: 11/21/08

Page: 1 of 5

Revised date: 7/27/09

Title:

Implantable Cardioverter Defibrillator

Description

A common complication of heart disease is the occurrence of an arrhythmia, which is an abnormality of the regular rhythmic beating of the heart. Some arrhythmias can be fatal by causing the heart to stop pumping. If this is not corrected within a few minutes, the result will be sudden cardiac death. The most common arrhythmias resulting in sudden death are ventricular fibrillation (in which the heart muscle quivers rather than contracting, causing blood flow to vital organs to stop), and ventricular tachycardia (which is a rapid but unstable heart rhythm which often deteriorates into ventricular fibrillation). Fortunately, when caught within the first few minutes of onset, both of these lethal rhythms can often be converted to a more normal rhythm that allows the heart to pump blood, thus increasing the likelihood of survival. This is accomplished by delivering an electrical shock to the heart muscle through electrodes that are attached to the heart internally (via a surgical procedure) or through the skin and tissues near the heart, using an external device. A defibrillator is a device consisting of a battery capable of producing a large electrical shock, connecting wires, and electrodes that deliver the electric shock to the heart muscle. The delivery of the shock is not timed to synchronize with the heart rhythm, since in ventricular fibrillation there is no rhythm. A cardioverter has the same components as the defibrillator, and in addition has a sensor that detects the heart rhythm and delivers a synchronized shock at the appropriate point in the contraction of the heart.

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. Indications for ICD implantation can be broadly subdivided into 1) secondary prevention, i.e., their use in patients who have experienced a potentially life-threatening episode of ventricular tachyarrhythmia (near sudden cardiac death); and 2) primary prevention; i.e., their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or VF.

When services are covered for all Plans including Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS Plus Rx

We cover the use of the automatic implantable cardioverter defibrillator (ICD) in patients who meet the following criteria:

Primary Prevention

- symptomatic* ischemic dilated cardiomyopathy with a history of myocardial infarction at least 40 days before ICD treatment and left-ventricular ejection fraction of 35% or less; or
- symptomatic* nonischemic dilated cardiomyopathy for more than 9 months' duration and left ventricular ejection fraction of 35% or less.
- hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior

unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.

* Symptomatic heart failure is defined as the presence of dyspnea on exertion, angina, palpitations, or fatigue.

Secondary Prevention

- Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia.

When services are not covered for all Plans including Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS Plus Rx

We do not cover the use of the ICD in primary prevention patients who:

- have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment);
- have New York Heart Association (NYHA) Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device);
- have had cardiac revascularization procedure in past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; or
- have non-cardiac disease that would be associated with life expectancy less than 1 year.

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed

Blue Cross Blue Shield of Massachusetts
Provider Appeals
PO Box 986065
Boston, MA 02298

Prior to performance of service

Blue Cross Blue Shield of Massachusetts
Case Creation/Medical Policy
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-327-6716
Fax: 1-888-641-5330

Managed care guidelines

- Any specialist visit requires a referral for **Medicare HMO Blue**.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO guidelines

All authorization requirements are determined by the individual's subscriber certificate, however:

- Authorizations are required for all inpatient services.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Medicare Policy Guidelines

In January 2005, Medicare issued the following revised national coverage guidelines for the use of ICDs. (11)

The Centers for Medicare and Medicaid Services (CMS) determined that the evidence is adequate to conclude that an ICD is reasonable and necessary for the following:

- Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF of 35% or less;
- Patients with NIDCM >9 months, NYHA Class II and III heart failure, and measured LVEF of 35% or less;
- Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;

For each of these groups, patients must not have:

- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- Had a CABG or PTCA within the past 3 months;
- Had an acute MI within the past 40 days;
- Clinical symptoms or findings that would make them a candidate for coronary revascularization;
- Irreversible brain damage from preexisting cerebral disease;
- Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;

In addition, CMS specifies that the beneficiary receiving the ICD implantation for primary prevention must be enrolled in either an FDA-approved category B Investigational Device Exemption clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a qualifying data collection system including approved clinical trials and registries.

The Medicare policy for ischemic and nonischemic dilated cardiomyopathy is consistent with this policy.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following code is included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

CPT Codes –

- **33216** - Insertion of transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
- **33217** - Dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator
- **33240** - Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator
- **33241** - Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator
- **33243** - Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
- **33244** - Removal by transvenous extraction
- **33245** - Insertion of epicardial single or dual chamber pacing cardioverter-defibrillator electrodes by thoracotomy;
- **33249** - Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator

HCPCS No Code
Type of Service Surgery
Place of Service Inpatient
See footnote ² for ICD 9 procedure to diagnosis codes.

Policy update history

12/08, New policy issued based on review of literature and decision that automatic implantable cardioverter defibrillators may be considered **medically necessary** for individuals who meet the stated criteria. 2/09, Codes updated and policy formatted post review of BCBSA policy # 7.01.44. No change in policy statement. 3/09, ICD-9-CM code updated to include 996.04. Reviewed 4/09 MPG – Cardiology, no changes in coverage were made.

Footnotes:

¹ Based on Blue Cross Blue Shield Association medical policy # 7.01.44, Implantable Cardioverter Defibrillator.

² ICD-9 CM Diagnoses codes:

- 425.1 - 425.4 - Hypertrophic cardiomyopathy codes
- 427.1 - Paroxysmal ventricular tachycardia
- 427.41 - Ventricular fibrillation
- 427.9 - Cardiac dysrhythmia, unspecified (ventricular arrhythmia code)
- 996.04 - Mechanical complication due to automatic implantable cardiac defibrillator

References:

References for footnote 1:

1. 2002 TEC Assessments; Tab 10.
2. 2004 TEC Assessments; Tab 19
3. Desai AS, Fang JC, Maisel WH et al. Implantable defibrillators for the prevention of mortality in patients with nonischemic cardiomyopathy—a meta-analysis of randomized controlled trials. *JAMA* 2004; 292(23):2874-9.
4. Raviele A, Bongiorno MG, Brignole M et al. Early EPS/ICD strategy in survivors of acute myocardial infarction with severe left ventricular dysfunction on optimal beta-blocker treatment. The Beta-blocker Strategy plus ICD trial. *Europace* 2005; 7(4):327-37.
5. Gregoratos G, Abrams J, Epstein AE et al. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation). *Circulation* 2002; 106(16):2145-61. Available at: <http://www.acc.org/clinical/guidelines/pacemaker/incorporated/index.htm> .
6. Hunt SA, Abraham WT, Chin MH et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). *J Am Coll Cardiol* 2005; 46(6):e1-82. Available at: <http://content.onlinejacc.org/cgi/reprint/46/6/1116> . Last accessed November 2007.
7. Zipes DP, Camm AJ, Borggrefe M et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Circulation* 2006; 114(10):e385-484.
8. Kadish A, Schaechter A, Subacius H et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. *J Am Coll Cardiol* 2006; 47(12):2477-82.

9. Maron BJ, Spirito P, Shen WK et al. Implantable cardioverter-defibrillators and prevention of sudden cardiac death in hypertrophic cardiomyopathy. JAMA 2007; 298(4):405-12.
10. Ellenbogen KA, Levine JH, Berger RD et al. Are implantable cardioverter defibrillator shocks a surrogate for sudden cardiac death in patients with nonischemic cardiomyopathy? Circulation 2006; 113(6):776-82.
11. Medicare policy: <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=148> .

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

©2009 Blue Cross and Blue Shield of Massachusetts, Inc. All rights reserved. Blue Cross and Blue Shield of Massachusetts, Inc. is an Independent Licensee of the Blue Cross and Blue Shield Association.