MASSACHUSETTS

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Medical Policy

Wearable Cardioverter Defibrillators

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Policy Number: 042

BCBSA Reference Number 2.02.15

Related Policies

- Implantable Cardioverter Defibrillator (ICD), #070

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **MEDICALLY NECESSARY** as interim treatment for those who have all of the following:

- Meet the criteria for an implantable cardioverter-defibrillator (see indications in Policy No. 070); and
- Have a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time; and
- Have been scheduled for an ICD placement or who had an ICD removed and have been rescheduled for placement of another ICD once the contraindication is treated.

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **INVESTIGATIONAL** for the following indications when they are the sole indication for a wearable cardioverter-defibrillator:

- Patients in the immediate (i.e., less than 40 days) period following an acute myocardial infarction
- Patients post-CABG [coronary artery bypass graft] surgery
- Patients with newly diagnosed nonischemic cardiomyopathy
- Women with peripartum cardiomyopathy
- High-risk patients awaiting heart transplant.

Use of wearable cardioverter-defibrillators is considered **INVESTIGATIONAL** for all other indications.

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Automatic external defibrillators are covered for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described under I or II. It is expected the ordering physician be experienced in the management of beneficiaries at risk for SCD.

I. A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the criteria (1-4), described below:
   1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction (ICD-9 427.1, 427.42, 427.5); or
   2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome (ICD-9 426.82) or hypertrophic cardiomyopathy (ICD-9 425.1); or
   3. Either documented prior myocardial infarction (ICD-9 410.00-410.92, 412) or dilated cardiomyopathy (ICD-9 425.0-425.9) and a measured left ventricular ejection fraction less than or equal to 0.35; or
   4. A previously implanted defibrillator now requires explantation (ICD-9 996.04, 996.61)

II. A nonwearable automatic defibrillator (E0617) is covered for beneficiaries in two circumstances. They meet either (1) both criteria A and B or (2) criteria C, described below:

III.

A. The beneficiary has one of the following conditions (1-8):

   1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause (ICD-9 427.41, 427.42, 427.5).
   2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause (ICD-9 427.1).
   3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrythmias such as long QT syndrome (ICD-9 426.82) or hypertrophic cardiomyopathy (ICD-9 425.1).
   4. Coronary artery disease with a documented prior myocardial infarction, (ICD-9 410.00 – 410.92, 412) with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;
      a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
      b. The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
   5. Documented prior myocardial infarction (ICD-9 410.00-410.92, 412) and a measured left ventricular ejection fraction less than or equal to 0.30. Beneficiaries must not have:
      a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or,
      b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or,
      c. Had an enzyme-positive MI within past month; or,
      d. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or,
      e. Irreversible brain damage from preexisting cerebral disease; or,
      f. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
   6. Beneficiaries with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) $\leq$ 35%.
   7. Beneficiaries with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF $\leq$ 35%.
   8. Beneficiaries who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure.

B. Implantation surgery is contraindicated.
C. A previously implanted defibrillator now requires explantation (ICD-9 996.04, 996.61).

Claims for defibrillators for other indications will be denied as not reasonable and necessary.

Local Coverage Determination (LCD): Automatic External Defibrillators (L13613)
*http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=13613&ContrId=137&ver=46&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+(16003%2c+DME+MAC)&s=24&DocType=Active&bc=AggAAAIAAAAAAA%3d%3d&*

Prior Authorization Information

See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

	Outpatient	Inpatient
Commercial Managed Care (HMO and POS)	No	n/a
Commercial PPO and Indemnity	No	n/a
Medicare HMO Blue℠	No	n/a
Medicare PPO Blue℠	No	n/a

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are 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. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
93292	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system)
93745	Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic electrocardiogram, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

HCPCS Codes

HCPCS codes:	Code Description
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, each
E0617	External defibrillator with integrated electrocardiogram analysis

ICD-9 Diagnosis Codes

ICD-9-CM diagnosis codes:	Code Description
414.8	Other specified forms of chronic ischemic heart disease
425.11	Hypertrophic obstructive cardiomyopathy
425.18	Hypertrophic cardiomyopathy
425.4	Other primary cardiomyopathies
427.1	Paroxysmal ventricular tachycardia
427.41	Ventricular fibrillation
427.9	Cardiac dysrhythmia, unspecified
996.04	Mechanical complication of automatic implantable cardiac defibrillator
996.61	Infection and inflammatory reaction due to cardiac device implant and graft

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
I25.5	Ischemic cardiomyopathy
I25.89	Other forms of chronic ischemic heart disease
I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.5	Other restrictive cardiomyopathy
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation
I49.9	Cardiac arrhythmia, unspecified
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter
T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.120A	Displacement of cardiac electrode, initial encounter
T82.121A	Displacement of cardiac pulse generator (battery), initial encounter
T82.128A	Displacement of other cardiac electronic device, initial encounter
T82.129A	Displacement of unspecified cardiac electronic device, initial encounter
T82.190A	Other mechanical complication of cardiac electrode, initial encounter
T82.191A	Other mechanical complication of cardiac pulse generator (battery), initial encounter
T82.198A	Other mechanical complication of other cardiac electronic device, initial encounter
T82.199A	Other mechanical complication of unspecified cardiac device, initial encounter
T82.6xxA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter
T82.7xxA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter
T82.7xxD	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, subsequent encounter
T82.7xxS	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, sequela

Description

A wearable cardioverter-defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter-defibrillator (ICD). It is primarily intended for temporary conditions for which an implantable device is contraindicated, or for a period of time during which the need for a permanent implantable device is uncertain.

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. The ICD has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of ICDs has been potentially broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction. ICDs consist of implantable leads in the heart that connect to a pulse generator implanted beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure, with the ICD device placed under the skin on the chest wall and the cardiac leads placed percutaneously. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See Policy No. 7.01.44 for further information on ICDs.

The WCD is an external device that is intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of a vest that is worn continuously underneath the patient's clothing. Part of this vest is the “electrode belt” that contains the cardiac-monitoring electrodes and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module that is worn on the patient’s belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages.

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001 for “adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator.” The vest was renamed and is now called the Zoll® LifeVest.®

Summary

The available data establish that the wearable cardioverter-defibrillator (WCD) device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. There are a small number of patients who meet established criteria for an implantable cardioverter-defibrillator (ICD) but have a transient contraindication for an implantable device, most commonly an infectious process. In these patients who are scheduled for ICD placement, the WCD may be considered medically necessary as an interim treatment. The evidence shows that these patients benefit from a cardioverter-defibrillator in general; and the WCD can detect and treat lethal arrhythmias in these patients.

For other bridging indications, particularly for the immediate postmyocardial infarction period, the evidence does not support the conclusion that the WCD improves outcomes. Two randomized controlled trials (RCTs) have reported that overall survival is not improved following treatment with a permanent ICD. While these 2 trials both reported a decrease in sudden cardiac death, there was a corresponding increase in non-SCD, resulting in no net benefit in survival. Similarly, for high-risk postcoronary artery bypass graft patients, 1 RCT reported no difference in overall survival associated with early ICD placement. Thus, given the lack of evidence that a permanent ICD improves outcomes for these indications, a WCD is not expected to improve outcomes and is therefore considered investigational.

For other potential indications, there are only case series or no relevant published evidence. Therefore it is not possible to conclude from the available evidence that net health outcome will be improved. These other indications, including bridge to transplantation, newly diagnosed nonischemic cardiomyopathy, and peripartum cardiomyopathy, are also considered investigational.

Policy History

Date	Action
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
6/2014	BCBSA National medical policy review. New investigational indications described. Effective 6/1/2014.
3/2014	BCBSA National medical policy review. New investigational indications described; title changed. Effective 3/1/2014. Coding information clarified
6/2013	New medically necessary indications for Medicare described. Effective immediately, 6/17/2013.
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2009	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2008	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
3/1/2008	Medical Policy 042 effective 3/1/2008, describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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