

# Medical Coverage Policy



## Wearable and Portable Cardioverter-Defibrillators-PREAUTH

☒ Device/Equipment ☐ Drug ☐ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	1/7/2012	Policy Last Updated:	4/2/2013
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☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

**This policy addresses the use of wearable and portable defibrillators only and does not include implantable defibrillators as they are covered.**

### Description:

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. The implantable cardioverter-defibrillator (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 connects 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.

The wearable cardioverter-defibrillator (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.

Wearable cardioverter-defibrillators for the prevention of sudden cardiac death are considered not medically necessary for all other indications, including use immediately (i.e., less than 40

days) following an acute myocardial infarction because the evidence does not support the conclusion that the WCD improves outcomes.

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.”

A portable nonwearable external defibrillator is a device that is used by someone other than the affected individual to effect defibrillation. It consists of a monitor, electrodes, and a small alarm module.

## **Medical Criteria:**

### **BlueCHiP for Medicare**

#### **WEARABLE DEFIBRILLATORS**

- I. A wearable defibrillator (K0606) is covered for patients if they meet **one** of the criteria (1-4):
  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; or
  2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
  3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
  4. A previously implanted defibrillator now requires explantation.

#### **PORTABLE DEFIBRILLATORS**

A portable external defibrillator is covered for patients who meet either both criteria A and B or criteria C, described below:

- A. The patient 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.
  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.
  3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.
  4. Coronary artery disease with a documented prior myocardial infarction, 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 and a measured left ventricular ejection fraction less than or equal to 0.30. Patients must not have one (1) of the following:

- 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. Patients 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. Patients with nonischemic dilated cardiomyopathy (NIDCM)  $>$  3 months, NYHA Class II and III heart failure, and measured LVEF  $\leq$  35%.

8. Patients 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 removal.

**NOTE:** Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates scientific evidence with local expert opinion, and consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. and the US Congress. BCBSRI policy is based upon peer-reviewed, scientifically controlled studies in the literature that demonstrate the superior health outcome of a service or treatment. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. BCBSRI and Medicare policies may differ, however, our BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers. (In some, but not all instances, BCBSRI offer more benefits than does Medicare).

### **Commercial Products only**

### **WEARABLE DEFIBRILLATORS**

Wearable cardioverter-defibrillators are considered medically necessary as interim treatment for the prevention of sudden cardiac death for candidates receiving the automatic implantable cardioverter defibrillator (ICD) for the following:

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less; or
- Ischemic cardiomyopathy with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; or
- Nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; or
- 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; or
- Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia; or
- 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.

## **PORTABLE DEFIBRILLATORS**

A portable external defibrillator is covered for patients in two circumstances. They meet either both criteria A and B or criteria C, described below:

- A. The patient 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.
  - 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.

3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.

4. Coronary artery disease with a documented prior myocardial infarction, 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 and a measured left ventricular ejection fraction less than or equal to 0.30. Patients must not have one (1) of the following:

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. Patients 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. Patients with nonischemic dilated cardiomyopathy (NIDCM)  $>$  3 months, NYHA Class II and III heart failure, and measured LVEF  $\leq$  35%.

8. Patients 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 removal.

**Policy:**

Preauthorization is required for Blue CHiP for Medicare and recommended for all other BCBSRI products.

Wearable cardioverter defibrillator and portable external defibrillator are covered when the medical criteria above are met.

Wearable and portable cardioverter defibrillators for all other indications not mentioned above in the criteria are considered not medically necessary as there is insufficient peer reviewed scientific literature to demonstrate that the device is effective.

**NOTE:** At the present time, Zoll LifeVest is the only provider of wearable defibrillators, and as they are non-participating, out of network copays can be waived when a request is determined to be medically necessary.

**Coverage:**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable Durable Medical Equipment coverage.

**Codes:**

The following codes **require preauthorization:**

**K0606** Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

**E0617** External defibrillator with integrated electrocardiogram analysis (portable)

**The following code is covered and will only pay when there is an approved rental for HCPCS code K0606.**

**93745**

**The following covered codes do not require preauthorization:**

**K0607** Replacement battery for automated external defibrillator, each no preauth

**K0608** Replacement garment for use with automated external defibrillator, each no preauth

**K0609** Replacement electrodes for use with automated external defibrillator, each no preauth

**93292**

**Related Topics:**

Total Artificial Hearts as Permanent Replacement Therapy

**Published:**

Provider Update, June 2013

Provider Update, March 2012

**References:**

Centers for Medicare and Medicaid Services: Local Coverage Determination (LCD) for Automatic EXTERNAL DEFIBRILLATORS (L13613).

Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for IMPLANTABLE Automatic DEFIBRILLATORS (20.4).

Blue Cross Blue and Shield Association Medical Policy Reference Manual Policy # 2.02.15  
Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator  
Placement.

[http://bluwebportal.bcbs.com/global\\_assets/special\\_content/medical\\_policy/policymanual/policy.html?pnum=20215](http://bluwebportal.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=20215)

Blue Cross Blue and Shield Association Medical Policy Reference Manual Policy # 7.01.44  
Implantable Cardioverter Defibrillator (ICD).

[http://bluwebportal.bcbs.com/global\\_assets/special\\_content/medical\\_policy/policymanual/policy.html?pnum=70144](http://bluwebportal.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=70144)

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Wearable cardioverter-defibrillator as a bridge to implantable cardioverter-defibrillator treatment. TEC Assessments 2010; Volume 25, Tab 2. Accessed 12/05/2011.

[http://bluwebportal.bcbs.com/global\\_assets/special\\_content/tec\\_assessments/VOL25/25\\_02.pdf](http://bluwebportal.bcbs.com/global_assets/special_content/tec_assessments/VOL25/25_02.pdf)

**Review History:**

4/2/2013: Annual review of the policy.

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