

## Corporate Medical Policy

### Wearable Cardioverter Defibrillators

<b>File Name:</b>	wearable_cardioverter_defibrillators
<b>Origination:</b>	10/2004
<b>Last CAP Review:</b>	10/2020
<b>Next CAP Review:</b>	10/2021
<b>Last Review:</b>	10/2020

#### **Description of Procedure or Service**

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Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. When a person's heart rhythm goes into an uncoordinated electrical activity called ventricular fibrillation, the heart twitches and cannot pump blood efficiently. This condition often accompanies severe heart attacks when the patient's heart appears to have stopped beating.

Defibrillators work by giving the heart a controlled electric shock, hopefully jolting it back into a regular rhythm. 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 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.

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, during which time a conscious patient can abort or delay the shock.

#### **Regulatory Status**

In 2001, The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via the premarket approval process 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®.

In 2015, the FDA approved the LifeVest® "for certain children who are at risk for sudden cardiac arrest, but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent."

#### **Related Policies**

Implantable Cardioverter Defibrillator

# Wearable Cardioverter Defibrillators

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will provide coverage for a wearable cardioverter defibrillator when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.**

## Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, certificate language should be reviewed before applying the terms of the policy.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

## When Wearable Cardioverter Defibrillators are covered

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Use of a wearable cardioverter defibrillator (WCD) for the prevention of sudden cardiac death is considered medically necessary as an interim treatment for the following:

- I. Meet the criteria for an implantable cardioverter defibrillator (*see CMP Implantable Cardioverter Defibrillator*); AND Either a or b
  - a) Patient has a temporary contraindication to receiving an implantable cardioverter defibrillator (ICD) or has had an ICD removed for a temporary contraindication (eg systemic infection), and has been scheduled for placement of an ICD once the temporary indication has been resolved, OR
  - b) Patient is awaiting heart transplantation (defined as on a waiting list) OR
  
- II. Patient has an ejection fraction less than or equal to 35% AND
  - a) Is within 40 days of a myocardial infarction\*; OR
  - b) Has newly diagnosed non-ischemic dilated cardiomyopathy\*; OR
  - c) Has secondary cardiomyopathy that is potentially reversible\*; OR
  - d) Has had revascularization, ie, coronary artery bypass grafting, percutaneous coronary angioplasty and/or stenting within the past 90 days\*.

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- Use of a WCD after a myocardial infarction (MI) without revascularization will be covered for 40 days from the initial diagnosis.
- Use of a WCD for newly diagnosed non-ischemic dilated cardiomyopathy or for secondary cardiomyopathy that is potentially reversible will be covered for 90 days from the time of diagnosis during guideline-directed medical therapy.
- Use of a WCD after revascularization, to include after an MI, will be covered for 90 days after the procedure.

## When Wearable Cardioverter Defibrillators are not covered

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Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered investigational for all other indications.

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## Policy Guidelines

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The evidence for individuals who have a temporary contraindication for an implantable cardioverter defibrillator (ICD) and who receive a wearable cardioverter defibrillator (WCD), includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. The available data have established that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. In these patients who are scheduled for ICD placement, the WCD is considered medically necessary as an interim treatment. The evidence shows that these patients benefit from a cardioverter-defibrillator; and the WCD can detect and treat lethal arrhythmias in these patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

It is uncommon for patients to have a temporary contraindication to ICD placement. The most common reason will be a systemic infection that requires treatment before the ICD can be implanted. The wearable cardioverter-defibrillator should only be used short-term while the temporary contraindication (e.g., systemic infection) is being clinically managed. Once treatment is completed, the permanent ICD should be implanted.

For bridging after myocardial infarction (MI), the data confirm the decrease in sudden cardiac arrest for those patients considered high-risk for ventricular arrhythmias. These patients may be receiving treatment for complications following an MI and have experienced VT/VF or cardiac arrest, but are not yet candidates for a permanent implantable device.

The American Heart Association has given IIb recommendation for use of a Wearable Cardioverter-Defibrillator (WCD) for patients newly diagnosed with non-ischemic cardiomyopathy (NICM) (Al-Khatib SM, and colleagues). A scientific advisory from the American Heart Association reports that the use of WCDs may be reasonable in patients with a heightened risk of SCD (Sudden Cardiac Death) that may resolve over time or treatment of left ventricular dysfunction to include patients newly diagnosed with non-ischemic dilated cardiomyopathy starting guideline-directed medical therapy. (Class IIb recommendation-level of evidence C) (Piccini, JP Sr. and colleagues). The evidence is sufficient to determine that the technology results in meaningful improvement in the net health outcome.

The results of the VEST trial (Vest Prevention of Early Sudden Death Trial, Olgin et al, 2018), demonstrated that the primary outcome of sudden death or death from ventricular tachyarrhythmia (arrhythmic death) at 90 days, was not significantly lower among patients with a recent MI and an ejection fraction of 35% or less, when wearing the WCD. Patients were randomized to the device plus guideline-directed therapy (n=1524) or guideline-directed therapy only (n=778). Mean EF was 28% and 84% of participants had undergone revascularization (PCI) during the index hospitalization. The patients in the device group wore the device for a median of 18 hours a day (3.8-22.7). Death from arrhythmia occurred in 1.6% of the device group and 2.4% of those in the control group (relative risk, 0.67; 95% CI 0.37 to 1.21; p=18).

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbnsnc.com](http://www.bcbnsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 93292, 93745, K0606, K0607, K0608, K0609*

BCBSNC 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.

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## Scientific Background and Reference Sources

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Medical Director review 11/2011

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# Wearable Cardioverter Defibrillators

Medical Director review 4/2015

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Medical Director review 5/2018

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Medical Director review 10/2018

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Specialty Matched Consultant Advisory Panel review 10/2019

Medical Director review 10/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.15, 06/2020

Specialty Matched Consultant Advisory Panel review 10/2020

Medical Director review 10/2020

## Policy Implementation/Update Information

### For Policy External Defibrillators

- 10/28/04 New policy issued. External defibrillators are considered investigational. References added. Notification 10/28/2004. Effective 1/6/2005.
- 01/06/05 Code 93745 added. Is considered investigational.
- 11/27/06 Additional information added to Policy Guidelines section to support continued Investigational status. CPT Codes updated. References updated. Specialty Matched Consultant Advisory review 10/ 23/06. No changes to policy coverage criteria. CPT codes updated.
- 4/23/07 Policy revised to indicate BCBSNC will provide coverage for a wearable cardioverter defibrillator when it is determined to be medically necessary because the medical criteria and guidelines noted in the policy have been met. Guidelines for AICD added to Policy Guidelines section. (adn)
- 4/7/08 Description section revised, deleted information regarding Automatic External Defibrillators (AEDs). References updated. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn)
- 01/05/09 CPT codes 93741 and 93742 deleted. Added code 93292.
- 5/11/10 Specialty Matched Consultant Advisory Panel review. Added “or is awaiting heart transplantation (defined as on a waiting list)” to When External Defibrillators are covered section. Removed Medical Policy number (mco)
- 5/10/11 Specialty Matched Consultant Advisory Panel review 4/2011. References updated. Included FDA information regarding the LifeCor WCD@2000 system. (mco)
- 11/22/11 Policy Guidelines for use of AICD updated. New **adult** primary prevention guidelines are as follows: “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

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- HCM.” New **pediatric** indications for AICDs are as follows: “The use of the ICD may be considered medically necessary in children who meet any of the following criteria: survivors of cardiac arrest, after reversible causes have been excluded; symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias. The use of the ICD is considered investigational for all other indications in pediatric patients.” References updated. Medical Director review 11/2011. Notification given 11/22/11 for effective date of 02/21/12. (mco)
- 5/15/12 Specialty Matched Consultant Advisory Panel review 4/2012. References updated. No changes to Policy Statements. (mco)
- 1/1/13 Removed information regarding Implantable Cardioverter Defibrillators from Policy Guidelines. Please refer to new policy titled “Implantable Cardioverter Defibrillators” effective 1/1/2012. Medical Director review 10/1/12. (mco)
- 5/14/13 References updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 4/2013. Medical Director review 4/2013.(mco)
- 10/1/13 Policy Guidelines updated. References updated. (mco)
- 2/25/14 Policy Guidelines updated. References updated. No changes to Policy Statements. (mco)
- 7/15/14 Specialty Matched Consultant Advisory Panel review 4/2014. “When Covered” section revised to include the following indications: “Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered medically necessary as a bridge to ICD placement for patients within 40 days post myocardial infarction (MI) who: have sustained ventricular tachycardia/ventricular fibrillation (VT/VF) occurring > 48 hours after index MI; **or** have a measured left ventricular ejection <35%; **or** have presented with out of hospital cardiac arrest.” “When not Covered” revised to state: “Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered investigational for all other indications. For patients who are post myocardial infarction (MI), use of the wearable cardioverter defibrillators is limited to forty days.” Policy Guidelines updated. References updated. Medical Director review 6/2014. (mco)
- 10/28/14 Added the following statement to the Benefits Application section: “The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.” (mco)
- 2/24/15 References updated. Policy Statements remain unchanged. (td)
- 5/26/15 References updated. Policy Statements remain unchanged. Specialty Matched Consultant Advisory Panel review 4/29/2015. Medical Director review 4/2015. (td)
- 7/1/15 Description section updated to remove archived guideline “Biventricular Pacemakers/Cardiac Resynchronization Therapy for Heart Failure”. (td)
- 5/31/16 Description section updated. Specialty Matched Consultant Advisory Panel review 4/27/2016. Medical Director review 4/2016. (jd)
- 7/1/16 Regulatory Status section added with update. References updated. Medical Director review 5/2016. (jd)
- 5/26/17 Minor revisions to Description section and Policy Guidelines. References updated. Specialty Matched Consultant Advisory Panel review 4/2017. Medical Director review 5/2017. (jd)
- 6/30/17 Minor revisions only. References updated. Medical Director review 5/2017. (jd)

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5/11/18 Minor revisions to Policy Guidelines. Specialty Matched Consultant Advisory Panel review 4/2018. Medical Director review 4/2018. (jd)

6/8/18 Policy guidelines and references updated. Medical Director review. (jd)

## **For Policy titled Wearable Cardioverter Defibrillators**

11/30/18 Policy title changed from *External Defibrillators* to *Wearable Cardioverter Defibrillators* for consistency. When Not Covered section revised with the following two bullets added under “Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered investigational for all other indications including: **patients who have undergone cardiac revascularization, ie., coronary artery bypass grafting, percutaneous coronary angioplasty and/or stenting, within the past 90 days** and **patients with newly diagnosed non-ischemic cardiomyopathy with an ejection fraction of 35% or less, during the initial 3 months of guideline directed therapy.**” Policy guidelines and references updated. Medical Director review 10/2018. (jd)

5/14/19 Policy statement revised; removed the non-covered statement regarding newly diagnosed non-ischemic cardiomyopathy and added this statement under bullet 4 under the When Covered section as follows: **“have newly diagnosed non-ischemic cardiomyopathy with an ejection fraction of 35% or less, during the initial 3 months of guideline directed therapy.”** Policy guidelines revised to align with policy statement, and references updated. Medical Director review 4/2019. (jd)

5/28/19 Minor revisions to the When Covered section for clarity; no change to policy intent. (jd)

7/16/19 When Covered section revised under items I and II and added the following under “\*” for clarification: “-Use of a WCD after a myocardial infarction (MI) without revascularization will be covered for 40 days from the initial diagnosis. -Use of a WCD for newly diagnosed non-ischemic dilated cardiomyopathy or for secondary cardiomyopathy that is potentially reversible will be covered for 90 days from the time of diagnosis during guideline-directed medical therapy. -Use of a WCD after revascularization, to include after an MI, will be covered for 90 days after the procedure.” Medical Director review 7/2019. (jd).

10/29/19 References updated. Specialty Matched Consultant Advisory Panel review 10/2019. Medical Director review 10/2019. (jd)

11/10/20 References updated. Specialty Matched Consultant Advisory Panel review 10/2020. Medical Director review 10/2020. (jd)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.