Introduction

Sudden cardiac arrest is when the heart stops beating. It can cause death within minutes if not treated. A cardiac defibrillator is a device that shocks the heart back into normal rhythm to prevent sudden cardiac arrest. A wearable cardiac defibrillator is one type of defibrillator. It’s strapped around the chest and worn underneath clothes. Electrodes (small patches applied to the skin) monitor the heart’s rhythm. Other electrodes deliver the current. The electrodes are attached to a small defibrillation unit, usually worn at the waist. When a life threatening heart rhythm is detected, an alarm alerts the person and the defibrillator sends a shock to return the heart to a normal rhythm. These vests are useful when surgery to implant a permanent defibrillator is temporarily delayed due to a medical reason. This policy describes when a wearable cardioverter-defibrillator may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Wearable cardioverter-defibrillator** | The use of a wearable (external) cardioverter-defibrillator (WCD) to prevent sudden cardiac arrest or death (SCD) may be considered medically necessary as a bridge to permanent implantable (internal) cardioverter-defibrillator (ICD) surgery or replacement of an ICD that was removed, when ALL of the following criteria are met:  
  - The criteria for an ICD placement is met (see Additional Coverage Criteria section)  
  AND  
  - A temporary contraindication to the ICD placement/replacement surgery exists such as when:  
    - A current systemic infection is being treated before the ICD can be placed  
    OR  
    - An ICD was removed due to a current infection that is being treated  
    OR  
    - A new onset of nonischemic cardiomyopathy is being treated medically for 90 days per American College of Cardiology and the American Heart Association (ACC/AHA) guidelines (see Additional Coverage Criteria section)  
  AND  
  - The ICD placement or an ICD replacement surgery, if appropriate, will be scheduled once the temporary contraindication is treated or managed. |

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wearable cardioverter-defibrillator</strong></td>
<td>Use of a wearable cardioverter-defibrillator for the prevention of sudden cardiac death (SCD) is considered investigational for all other indications not listed in the Medical Necessity section above, including immediately (ie, less than 40 days) following an acute myocardial infarction (AMI).</td>
</tr>
</tbody>
</table>
Additional Coverage Criteria

Temporary Contraindications for ICD placement

A short-lived or temporary contraindication to implantable cardioverter-defibrillator (ICD) placement occurs infrequently. Reasons for temporary use of the wearable (external) cardioverter-defibrillator (WCD) include:

- While a current systemic infection is being treated before the ICD can be placed or
- When an ICD was removed due to a current infection with plans for a replacement after the infection resolves or
- While a new onset of nonischemic cardiomyopathy is being treated medically for 90 days per ACC/AHA guidelines.

Note: If the patient with nonischemic cardiomyopathy responds to maximal medical treatment after 90 days, and ICD surgery is cancelled, coverage for the WCD will stop.

American College of Cardiology and the American Heart Association (ACC/AHA)

The ACC/AHA Guidelines state that immediate ICD placement is contraindicated for nonischemic cardiomyopathy until the patient has had maximal medical treatment for 90 days. In some cases the condition improves with medical treatment and the ICD placement is no longer necessary.

Indications for Implantable Cardioverter-Defibrillator (ICD) implantation

Indications for ICD implantation can be broadly subdivided into two categories:

1. Primary prevention, in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening ventricular arrhythmia such tachycardia (VT) or ventricular fibrillation (VF).
2. Secondary prevention, in patients who have experienced a life-threatening episode of VT, after reversible causes have been excluded.

Primary Prevention criteria for the use of the automatic ICD in adults includes:

- 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
Additional Coverage Criteria

- Nonischemic dilated cardiomyopathy (NIDCM) 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 one or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in one or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; one or more runs of non-sustained 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.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>93292*</td>
<td>Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system</td>
</tr>
<tr>
<td>93745</td>
<td>Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>K0606</td>
<td>Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
</tr>
<tr>
<td>K0607</td>
<td>Replacement battery for automated external defibrillator, garment type only, each</td>
</tr>
<tr>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
</tr>
<tr>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
</tr>
</tbody>
</table>

*Code 93292 cannot be reported with code 93745.

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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.

The WCD performs the monitoring and electrical shocks like an ICD, when a potential life-threatening heart rhythm is detected, without requiring an invasive procedure. The system 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. (See Appendix for graphic.)

Some patients with coronary artery disease may suddenly die of a heart rhythm disorder. 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, 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 and reduced ejection fraction.

Background

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 is an external device that is intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of a vest 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 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.

**Summary of Evidence**

For individuals who have a temporary contraindication for an implantable cardioverter defibrillator (ICD) who receive a wearable cardioverter defibrillator (WCD), the evidence includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The available data establish that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. 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. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence has shown that these patients benefit from a cardioverter defibrillator in general, and the WCD can detect and treat lethal arrhythmias in these patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who are in the immediate post myocardial infarction period who receive a WCD, the evidence includes randomized controlled trials (RCTs) and a technology assessment. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For the immediate post myocardial infarction period, the evidence does not support the conclusion that the WCD improves outcomes. Two RCTs have reported that overall survival did not improve after treatment with a permanent ICD. While these 2 trials both reported a decrease in sudden cardiac death (SCD), there was a corresponding increase in non-SCD, resulting in no net survival benefit. Similarly, for high-risk post coronary 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are post coronary artery bypass graft surgery and at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, or have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes case series and registry data. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment–related morbidity. It is not possible to conclude from the available evidence that the WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1: Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01446965a</td>
<td>Prevention of Sudden Death After Myocardial Infarction Using a LifeVest Wearable Cardioverter-defibrillator</td>
<td>1900</td>
<td>Dec 2017</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
2014 Input

In response to requests, further input was received from 7 academic medical centers and 2 physician specialty societies while this policy was under review in 2014. Input related to the role of WCDs in preventing SCD among high-risk patients awaiting a heart transplant. Overall, input on the use of WCDs in this patient population was mixed. Some reviewers indicated that it may have a role among certain patients awaiting heart transplant, but there was no consensus on specific patient indications for use.

2013 Input

In response to requests, input was received from 8 academic medical centers and 3 physician specialty societies while this policy was under review in 2013. Overall, the input was mixed. Most, but not all, providing comments suggested that the WCD may have a role in select high-risk patients following acute MI or in newly diagnosed cardiomyopathy. However, reviewers acknowledged the lack of evidence for benefit and that available evidence was not consistent in defining high-risk subgroups that may benefit.

2010 Input

In response to requests, input was received from 4 academic medical centers and no physician specialty societies while this policy was under review in 2010. Most, but not all, providing comment suggested that the WCD may have a role in selected high-risk patients following acute MI or in newly diagnosed cardiomyopathy.

Practice Guidelines and Position Statements

American College of Cardiology and the American Heart Association (ACC/AHA)

In 2016, the American Heart Association (AHA) published a scientific advisory on the wearable cardioverter defibrillator (WCD). AHA stated that “because there is a paucity of prospective data supporting the use of the WCD, particularly in the absence of any published, randomized, clinical trials, the recommendations provided in this advisory are not intended to be prescriptive
or to suggest an evidence-based approach to the management of patients with FDA-approved indications for use.” The specific recommendations are summarized in Table 2.

### Table 2. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection.”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>“Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>“Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction/ for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable.”</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>“WCDs may be appropriate as bridging therapy in situation associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 D of MI.”</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>“WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive &gt;6 mo.”</td>
<td>III</td>
<td>C</td>
</tr>
</tbody>
</table>

AHA: American Heart Association; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

### Heart Rhythm Society, American College of Cardiology and the American Heart Association (ACC/AHA)

In 2014, the Heart Rhythm Society, ACC, and AHA issued a consensus statement on the use of ICD therapy in patients who are not included or not well-represented in clinical trials.29 The statement does not contain formal recommendations on WCD use, but states: “The wearable cardioverter-defibrillator (WCD) may be an option as a ‘bridge to ICD’ for selected patients at high risk of sudden cardiac death due to ventricular arrhythmias, although the data are scant.”

In 2014, ACC and AHA issued guidelines on the management of non-ST-elevation acute coronary syndrome (NSTE-ACS).30 These guidelines do not make specific recommendations regarding the use of WCDs, but do state the following:

Life-threatening ventricular arrhythmias that occur >48 hours after NSTE-ACS are usually associated with LV [left ventricular] dysfunction and signify poor prognosis. RCTs [randomized controlled trials] in patients with ACS [acute coronary syndrome] have shown consistent benefit of implantable cardioverter-defibrillator therapy for survivors of VT
[ventricular tachycardia] or VF [ventricular fibrillation] arrest. For other at-risk patients, especially those with significantly reduced LVEF [left ventricular ejection fraction], candidacy for primary prevention of sudden cardiac death with an implantable cardioverter-defibrillator should be readdressed ≥40 days after discharge. A life vest may be considered in the interim.

**International Society for Heart and Lung Transplantation**

In 2006, the International Society for Heart and Lung Transplantation issued guidelines for the care of cardiac transplant candidates that addressed use of ICDs or WCDs.\(^\text{31}\) Recommendations related to the use of WCDs include:

- **Class I recommendations:** “An implanted or wearable ICD should be provided for Status 1B patients [ie, dependent on intravenous medications or a mechanical assist device] who are discharged home given that the wait for transplantation remains significant (Level of Evidence: C).”

- **Class IIa recommendations:** “It is reasonable to consider placement of a defibrillator in patients with Stage D failure who are candidates for transplantation or LVAD [left ventricular assist device] destination therapy (see subsequent considerations for mechanical circulatory support device [MCSD] referral: bridge or destination) (Level of Evidence: C).”

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Noridian Healthcare Solutions, LLC**

Noridian Healthcare Solutions, LLC the contractor for jurisdiction D has an LCD for Automatic External Defibrillators (L13690) that includes coverage criteria for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described in the coverage guideline.\(^\text{33}\)
Regulatory Status

In December 2001, the Lifecor WCD® 2000 system was approved by the U.S. Food and Drug Administration (FDA) through 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 the Zoll® LifeVest®.

In 2015, 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.”

FDA product code: MVK.

References


3. 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.


10. Goldenberg I KH, Zareba W et al. Eighteen Month Results From The Prospective Registry And Follow-up Of Patients Using The Lifevest Wearable Defibrillator (WEARIT-II Registry) - LB02-02. Heart Rhythm 2013 - 34th Annual Scientific Sessions; May 10, 2013.


Appendix

Selected components of the wearable cardioverter-defibrillator

Garment/Electrode Belt Assembly

Battery Charger

Power Supply

Battery Pack

Battery Charger

Alarm Module

Monitor
### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/13/12</td>
<td>New Policy. Premera policy created to include in the policy statement, information about when coverage for the WCD will stop; and to maintain the allowance of newly diagnosed nonischemic cardiomyopathy (as explained in the Policy Guidelines) as an indication for the temporary use of the WCD. The Policy Guidelines statement on nonischemic cardiomyopathy was changed to investigational in the October 2012 version of BCBSA policy 2.02.15. Therefore, Policy 2.02.15 is deleted.</td>
</tr>
<tr>
<td>12/09/13</td>
<td>Replace policy. Policy updated with literature review. References 6, 7, 13, 15 added. No change to policy statement.</td>
</tr>
<tr>
<td>03/25/14</td>
<td>Replace policy. Policy statement unchanged. References 5, 6 added. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in adjudication.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Interim review. Added primary prevention criteria found in 7.01.44 to the Policy Guidelines section.</td>
</tr>
<tr>
<td>12/01/14</td>
<td>Update Related Policies. Remove 2.02.10 as it was archived.</td>
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<tr>
<td>03/31/15</td>
<td>Annual Review. Policy statements unchanged. References 8,17,23,26,27,28 added.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Interim review. Policy statement and policy guidelines rewritten for clarification. Reference 28 the Noridian LCD on WCD for jurisdiction D added; others renumbered. Policy statements revised as noted, intent is unchanged.</td>
</tr>
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<td>12/15/15</td>
<td>Update Related Policies. Remove 7.01.44 as it is archived.</td>
</tr>
<tr>
<td>04/01/16</td>
<td>Update Related Policies Removed 2.02.505 as it was archived.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. Policy updated with literature review through March 22, 2016; references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/07/16</td>
<td>Minor formatting update. Updated hyperlink in reference number 1.</td>
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</table>

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  - Information written in other languages

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Email AppealsDepartmentinquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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