**Medical Benefit**

**Effective Date:** 08/01/17  
**Next Review Date:** 05/18

| Preauthorization | Review Dates: 05/07, 05/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 05/14, 05/15, 05/16, 05/17 | Preauthorization is required. |

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
• With a temporary contraindication to an implantable cardioverter defibrillator | Interventions of interest are:  
• Wearable cardioverter defibrillator | Comparators of interest are:  
• Usual clinical care | Relevant outcomes include:  
• Overall survival  
• Morbid events  
• Functional outcomes  
• Treatment-related morbidity |
| Individuals:  
• Who are in the immediate post myocardial infarction period | Interventions of interest are:  
• Wearable cardioverter defibrillator | Comparators of interest are:  
• Usual clinical care | Relevant outcomes include:  
• Overall survival  
• Morbid events  
• Functional outcomes  
• Treatment-related morbidity |
| Individuals:  
• Who are post coronary artery bypass graft surgery and at high risk for lethal arrhythmias | Interventions of interest are:  
• Wearable cardioverter defibrillator | Comparators of interest are:  
• Usual clinical care | Relevant outcomes include:  
• Overall survival  
• Morbid events  
• Functional outcomes  
• Treatment-related morbidity |
| Individuals:  
• Who are awaiting heart transplantation and are at high risk for lethal arrhythmias | Interventions of interest are:  
• Wearable cardioverter defibrillator | Comparators of interest are:  
• Usual clinical care | Relevant outcomes include:  
• Overall survival  
• Morbid events  
• Functional outcomes  
• Treatment-related morbidity |
| Individuals:  
• With newly diagnosed nonischemic cardiomyopathy | Interventions of interest are:  
• Wearable cardioverter defibrillator | Comparators of interest are:  
• Usual clinical care | Relevant outcomes include:  
• Overall survival  
• Morbid events  
• Functional outcomes  
• Treatment-related morbidity |
| Individuals:  
• With peripartum cardiomyopathy | Interventions of interest are:  
• Wearable cardioverter defibrillator | Comparators of interest are:  
• Usual clinical care | Relevant outcomes include:  
• Overall survival  
• Morbid events  
• Functional outcomes  
• Treatment-related morbidity |
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.

Summary of Evidence
For individuals who have a temporary contraindication for an ICD who receive a WCD, the evidence includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The available data have established 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. Studies have shown that these patients benefit from a cardioverter defibrillator in general, and the WCD can detect and treat lethal arrhythmias in them. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who 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.

Policy
Use of wearable cardioverter-defibrillators (WCDs) for the prevention of sudden cardiac death is considered medically necessary as interim treatment for those who:

- meet the criteria for an implantable cardioverter-defibrillator (ICD; refer to the Implantable Cardioverter Defibrillator Protocol) and:
  - have a temporary contraindication to receiving an ICD (i.e., 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;
- are in the ICD waiting period (i.e., less than 40 days) following an acute myocardial infarction;
- are in the ICD waiting period (i.e., less than 90 days) following coronary revascularization procedures such as coronary artery bypass graft surgery or percutaneous coronary intervention;
- are awaiting heart transplant and are considered at high risk for lethal arrhythmias.

Use of WCDs 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 with newly diagnosed nonischemic cardiomyopathy
- Women with peripartum cardiomyopathy

Use of WCDs is considered investigational for all other indications.
Policy Guidelines
A WCD would continue to be appropriate beyond a 90 day period when the patient is compliant with use of the device and when a re-assessment has been documented including review of both the continued need for ICD implantation and the current medical regime. Compliance would be demonstrated by a wear time of 22 hours per day (≥ 90%) during the preceding 30 days.

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.

Medicare Advantage
A wearable defibrillator is medically necessary for patients at high risk for sudden cardiac death (SCD) 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; 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.

All other indications for Medicare Advantage members are considered not medically necessary.

Background
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, 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.

ICDs consist of implantable leads which are placed percutaneously in the heart that are connected to a pulse generator implanted beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. Please see the Implantable Cardioverter Defibrillator Protocol for further information on ICDs.

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.
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.

Related Protocol

Implantable Cardioverter Defibrillator

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


