

<b>Medical Benefit</b>		<b>Effective Date:</b> 08/01/17	<b>Next Review Date:</b> 05/21
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 05/07, 05/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 05/14, 05/15, 05/16, 05/17, 07/17, 05/18, 05/19, 05/20	

**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.*

Populations	Interventions	Comparators	Outcomes
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 the period during which the need for a permanent implantable device is uncertain.

## SUMMARY OF EVIDENCE

### TEMPORARY CONTRAINDICATIONS

For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies. The relevant outcomes are overall survival (OS), 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 patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

#### Immediate Post Myocardial Infarction

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 that assess ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs have reported that OS did not improve after treatment with a permanent ICD. While both trials reported a decrease in sudden cardiac death, there was a corresponding increase in non-sudden cardiac death events, resulting in no net survival benefit. Analysis of data from a retrospective post-market registry with WCD reported a success rate of 82% but interpretation of registry data is limited in absence of a control group. Given the lack of evidence that a permanent ICD improves outcomes in the immediate post myocardial infarction period, a WCD would not be expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### Other High-Risk Conditions

For individuals who are post coronary artery bypass graft surgery and are at high-risk for lethal arrhythmias, awaiting heart transplantation and at high-risk for lethal arrhythmias, have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes an RCT evaluating early ICD placement after coronary artery bypass graft, and case series and registry data for other indications that assess ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, an RCT reported no difference in OSs associated with early ICD placement. For other indications, there are no RCTs that demonstrate benefit of an ICD placement. Because of absence of any benefit of ICD and lack of any RCTs to demonstrate benefit of a WCD, the evidence does not currently permit conclusions that a 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 Defibrillators 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

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)

SCA is the most common cause of death in patients with coronary artery disease.

## Treatment

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 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 placed beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See the Implantable Cardioverter Defibrillators Protocol for further information on ICDs.

The wearable cardioverter defibrillator (WCD) is an external device intended to perform the same tasks as an ICD, without 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.

U.S. Food and Drug Administration (FDA)-labeled indications for the WCD are adults at risk for SCA and either are not candidates for or refuse an implantable ICD.<sup>1</sup> Some experts have suggested that the indications for a WCD should be broadened to include other populations at high-risk for SCA.<sup>2</sup> The potential indications include:

- Bridge to transplantation (i.e., the WEARIT study population)
- Bridge to implantable device or clinical improvement (i.e., the BIROAD study population)
- Post bypass with ejection fraction less than 30%
  - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
  - Post myocardial infarction with ejection fraction less than 30%
  - Post myocardial infarction with ventricular arrhythmias within 48 hours
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

## REGULATORY STATUS

In 2001, the Lifecor WCD® 2000 system was approved by the 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, 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."

FDA product code: MVK.

**RELATED PROTOCOL**

## Implantable Cardioverter Defibrillators

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

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32. Noridian Healthcare Solutions, LLC, (Jurisdiction A - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont , District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania) Local Coverage Determination (LCD): Automatic External DEFIBRILLATORS (L33690), Revision Effective Date for services performed on or after 01/01/2020.