FEP 2.02.15 Wearable Cardioverter Defibrillators

Wearable Cardioverter Defibrillators

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.

OBJECTIVE

The objective of this evidence review is to assess whether the use of a wearable cardioverter defibrillator improves net health outcome in patients with a temporary contraindication to implantable cardioverter defibrillator or as a bridge to implantable cardioverter defibrillator placement or heart transplantation, or recovery.

POLICY STATEMENT

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); and
- 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.
Use of WCDs for the prevention of sudden cardiac death is considered **not medically necessary** for the following indications when they are the sole indication for a WCD:

- Patients in the immediate (ie, <40 days) period following an acute myocardial infarction
- Patients post coronary artery bypass graft surgery
- High-risk patients awaiting heart transplant
- Patients with newly diagnosed nonischemic cardiomyopathy
- Women with peripartum cardiomyopathy.

Use of WCDs is considered **not medically necessary** for all other indications.

**POLICY GUIDELINES**

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

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA 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.

**RATIONALE**

**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 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 MI**

For individuals who are in the immediate post MI period who receive a WCD, the evidence includes 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 SCD, there was a corresponding increase in non-SCD events, resulting
in no net survival benefit. Analysis of data from a retrospective postmarket 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 CABG 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 CABG, 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 CABG patients, an RCT reported no difference in OS 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Heart Association et al

The AHA, the American College of Cardiology and the Heart Rhythm Society (2018) published a guideline on the management of patients with ventricular arrhythmias and prevention of sudden cardiac death. The guidelines note that "the patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the wearable cardioverter-defibrillator. Patients with recent MI, newly diagnosed NICM, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT/SCA. However, the wearable cardioverter-defibrillator is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time." The specific recommendations are summarized in Table 1. Class IIa is moderate recommendation, and class IIb is a weak recommendation.

Table 1. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
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<tr>
<td>&quot;In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD.&quot;</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
<tr>
<td>&quot;In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed, NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable.&quot;</td>
<td>IIb</td>
<td>B-NR</td>
</tr>
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B-NR: Level B - nonrandomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NICM: non-ischemic cardiomyopathy; SCA: sudden cardiac arrest; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

The AHA (2016) published a scientific advisory on the WCD. The 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..."

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B-NR: data derived from ≥1 nonrandomized trials or meta-analysis of such studies; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; WCD: wearable cardioverter defibrillator.

a Removal of an ICD for a period of time, most commonly due to infection, exposes the patient to risk of untreated ventricular tachycardia/sudden cardiac death unless monitoring and access to emergency external defibrillation is maintained. In 1 series of 354 patients who received the WCD, the indication was infection in 10%. For patients with a history of sudden cardiac arrest or sustained ventricular arrhythmia, the WCD may allow the patient to be discharged from the hospital with protection from ventricular tachycardia/sudden cardiac death until the clinical situation allows reimplantation of an ICD.

b The patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the WCD. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of ventricular tachycardia or sudden cardiac death. However, the WCD is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time. In patients awaiting transplant, even with anticipated survival <1 year without transplant, and depending on clinical factors such as use of intravenous inotropes and ambient ventricular arrhythmia, a WCD may be an alternative to an ICD.

International Society for Heart and Lung Transplantation

The International Society for Heart and Lung Transplantation (2006) issued guidelines on the care of cardiac transplant candidates that addressed use of ICDs or WCDs. Recommendations on the use of WCDs are provided in Table 4.

Table 4. Guidelines on Management of Cardiac Transplant Candidates With ICDs

<table>
<thead>
<tr>
<th>Recommendation</th>
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<tr>
<td>&quot;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.&quot;</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>&quot;It is reasonable to consider placement of a defibrillator in patients with Stage D failure who are candidates for transplantation or LVAD destination therapy (see subsequent considerations for MCSD referral: bridge or destination).&quot;</td>
<td>Ila</td>
<td>C</td>
</tr>
</tbody>
</table>

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVAD: left ventricular assist device; MCSD: mechanical circulatory support device.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

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<thead>
<tr>
<th>Date</th>
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<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy updated with literature review, reference 6 updated, reference 14 added. Wording “have all of the following” stricken from medically necessary policy statement. No other changes to policy statement.</td>
</tr>
<tr>
<td>December 2012</td>
<td>Replace policy</td>
<td>Policy updated with literature review through August 2013, references 6-7, 13 and 15 added. No change to policy statement. Removed “as a Bridge to Implantable Cardioverter-Defibrillator Placement” from the title.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through November 30, 2014. References 17, 23, and 26-27 added. Investigational policy statements changed to not medically necessary.</td>
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<tr>
<td>September 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review, references 13, 20, 30-32 added. FDA regulatory status updated. Policy statements and guideline revised.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 14, 2018; reference 27-28 added; reference 1 updated. “High-risk patients awaiting heart transplant” was added to the not medically necessary policy statement; and an additional policy statement that use of wearable cardioverter-defibrillators is considered not medically necessary for all other indications was added.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 4, 2019.; reference 31 added. Policy statements unchanged.</td>
</tr>
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</table>

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