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Wearable Cardioverter Defibrillators

Summary

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.

For individuals who have a temporary contraindication to 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 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, 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.
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Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia after reversible causes (e.g., acute ischemia) have been excluded. (See Policy Guidelines)

FDA 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.

POLICY STATEMENT

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death may be considered medically necessary as interim treatment for patients with the following indications:

- Meet the criteria and guidance in policy 7.01.44 Implantable Cardioverter Defibrillator, including:
  - Patients with a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time, Or
  - Patients who 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, 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 HCM Or
  - Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
    - congenital long QT syndrome; OR
    - Brugada syndrome; OR
    - short QT syndrome; OR
    - catecholaminergic polymorphic ventricular tachycardia. or
  - Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia after reversible causes (e.g., acute ischemia) have been excluded.

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death may be considered medically necessary as interim treatment patients that are high-risk patients awaiting heart transplantation.

See Policy Guidelines below.
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Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered not medically necessary for all other indications, including but not limited to:

- Patients in the immediate (i.e., less than 40 days) period following an acute myocardial infarction, without ventricular tachyarrhythmia and LV EF <35%
- Patients post-CABG [coronary artery bypass graft] surgery
- In the absence of documented arrhythmias, patients with newly diagnosed non-ischemic cardiomyopathy (less than 3 months duration)

POLICY GUIDELINES

The 2016 American Heart Association Science Advisory, Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death provides recommendations for the use of WCDs as a bridge for individuals at risk for sudden cardiac deaths who are not immediate candidates for ICD placement.

“The most obvious candidates (for WCD) are those with a history of cardiac arrest or sustained ventricular tachyarrhythmias, in whom ICDs are effective. ICDs are also beneficial for the primary prevention of SCD in patients with certain forms of structural heart disease associated with risk of malignant arrhythmias (such as hypertrophic cardiomyopathy) or primary electric disease (such as long-QT syndrome) and in those with significantly impaired left ventricular systolic function. The last group includes patients with ischemic or nonischemic heart disease and a persistently depressed left ventricular ejection fraction (LVEF) ≤0.35 combined with New York Heart Association (NYHA) functional class II to III heart failure despite long-term guideline-directed medical therapy or a prior MI and an ejection fraction ≤0.30 in the absence of severe (NYHA functional class IV) heart failure and who are >40 days from their MI. These FDA-approved indications are based on and supported by pivotal trials that confirmed a survival benefit from an ICD in these populations.”

The 2016 AHA Science Advisory recommendations using WCDs for sudden cardiac death prevention:

- 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.
- Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation.
- 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 non-ischemic 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.
- WCDs may be appropriate as bridging therapy in situations 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.
- WCDs should not be used when non-arrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 mo.

See the related policy 7.01.44 Implantable Cardioverter Defibrillator.
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RATIONALE

The available evidence on the wearable cardioverter defibrillator (WCD) consists of case series describing outcomes from patients using the device. There are no published randomized controlled trials (RCTs) comparing WCD to standard care or alternative treatments. RCTs of patients undergoing permanent implantable cardioverter defibrillator (ICD) implantation can provide indirect evidence on the efficacy of the WCD if the indications for a permanent ICD are similar to the potential indications for WCD and if the performance of the WCD has been shown to approximate that of a permanent ICD.

U.S. Food and Drug Administration (FDA) labeled indications for the WCD are adult patients who are at risk for sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD. Additionally, in 2015 the FDA granted premarket approval for a WCD for patients under 18 years of age at risk for sudden cardiac arrest that meet chest circumference and weight benchmarks. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. The potential indications include: bridge to transplantation (ie, the WEARIT population); bridge to implantable device or clinical improvement (ie, the BIROAD population); post bypass with ejection fraction (EF) less than 30%; post bypass with ventricular arrhythmias or syncope within 48 hours of surgery; post myocardial infarction with EF less than 30%; post myocardial infarction (MI) 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; and patients who refuse device therapy.

WCD Effectiveness Compared With ICD Effectiveness

Very few peer-reviewed studies have reported on clinical outcomes of WCDs and none has evaluated the efficacy of WCD in reducing mortality compared with alternatives. Despite the small amount of evidence, a 2010 TEC Assessment found concluded that the evidence is sufficient to conclude the WCD can successfully terminate malignant ventricular arrhythmias. Assessment conclusions were based on several factors. First, there is strong physiologic rationale for the device. It is known that sensor leads placed on the skin can successfully detect and characterize arrhythmias. It is also established that a successful countershock can be delivered externally. The use of external defibrillators is extensive, ranging from in-hospital use to public placement and use at home. Its novelty is in the way that the device is packaged and utilized.

Second, there is some evidence that the device successfully terminates arrhythmias. Two uncontrolled studies were identified that directly tested the efficacy of the WCD. The first was a small case series (15 patients) of survivors of SCA scheduled to receive an ICD. During the procedure to implant a permanent ICD, or to test a previously inserted ICD, patients wore the WCD while clinicians attempted to induce ventricular arrhythmias. Of the 15 patients, 10 developed ventricular tachycardia (VT) or ventricular fibrillation (VF). The WCD correctly detected the arrhythmia in 9 of 10 cases and successfully terminated the arrhythmia in 9 cases. In 2010, Chung et al published an evaluation of WCD effectiveness in preventing sudden death based on a post market release registry of 3569 patients who received a WCD. Investigators found an overall successful shock rate of 99% for VT or VF (79/80 cases of VT or VF among 59 patients). Fifty-two percent of patients wore the device for more than 90% of the day. Eight patients died after successful conversion of VT/VF.

In 2014, Tanawuttiwat et al reported the results of a retrospective, uncontrolled evaluation of 97 patients who received a WCD after their ICD was explanted due to device infection. Subjects wore the device for a median of 21 days; during the study period, 2 patients had 4 episodes of arrhythmia appropriately terminated by the WCD, 1 patient experienced 2 inappropriate treatments, and 3 patients experienced sudden death outside the hospital while not wearing their WCD device.

The WEARIT/BIROAD study evaluated a prospective cohort of 289 patients at high risk for sudden cardiac death (SCD) but who did not meet criteria for an ICD or who could not receive an ICD for several months. Patients were followed for a mean of 3.1 months. During this time, there were 8 documented episodes of arrhythmia requiring shock in 6 separate patients. Six of the 8 episodes were successfully
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resuscitated by the WCD. By group sequential analysis, the estimate of percent successful resuscitations was 69%. There was 99% confidence that the true rate of success was greater than 25% and 90% confidence that the true rate was greater than 44%. In the 2 cases of unsuccessful defibrillation, the authors reported that the WCD was placed incorrectly, with the therapy electrodes reversed and not directed to the skin.

The WEARIT/BIROAD results underscore the difficulty in proper device use and compliance. Six patients suffered SCA likely due to wearing the device improperly or not wearing the device at all. This implied that a relatively high rate of nonadherence might be the main factor limiting the effectiveness of the WCD. In addition, there was a fairly high rate of dropout (22%) over the 3-month follow-up. In a study of 134 consecutive, uninsured patients with cardiomyopathy and a mean EF of 22.5%, Mitrani et al reported noncompliance with a WCD was even greater. The dropout rate was 35%. The WCD was never used by 8 patients, and only 27% wore the device more than 90% of the day. Patients who were followed for 72 days wore the WCD for a mean of 14.1 hours per day. Additionally, during follow-up, no arrhythmias or shock were detected. In a prospective registry of 82 heart failure patients eligible for WCDs, Kao et al reported that 13 patients did not wear the WCD due to refusal, discomfort, or other/unknown reasons. These results suggest that the WCD is likely to be inferior to an ICD, due to suboptimal adherence and difficulty with correct placement of the device. Therefore, these data corroborate the assumption that the WCD should not be used as a replacement for an ICD but only considered in those situations in which the patient does not meet criteria for a permanent ICD.

Another potential indication is for patients who are being evaluated for ICD placement. Clinical outcomes for patients prescribed a WCD for a transient or undefined arrhythmia risk who were prospectively enrolled in the WEARIT-II registry were published in abstract form in 2013, with 3-month results published in 2015. WEARIT-II enrolled 2000 patients with ischemic (n=805) or nonischemic cardiomyopathy (n=927) or congenital/inherited heart disease (n=268) who had been prescribed a WCD for risk assessment. The median wear time was 90 days, with a median daily use of 22.5 hours. The high compliance rate in this study may have been related to greater compliance in patients who volunteered to participate in the registry. During the WCD trial period, there were 120 sustained ventricular tachyarrhythmias in 41 patients. Ninety of the events were withheld from shock therapy by the patients and 30 required shock therapy. Appropriate shock was received by 22 (54%) of the 41 patients, while 10 (0.5%) patients received inappropriate shock. Three patients died while wearing the WCD, all from asystole. No patients died from VT or VF while wearing the WCD. At the end of the evaluation period, 42% of patients received an ICD and 40% of patients were no longer considered to need an ICD, most frequently because EF improved. Follow-up of clinical outcomes is continuing through 12 months.

Section Summary: WCD Effectiveness Compared With an ICD Effectiveness

No studies have directly compared the performance of a WCD to a permanent ICD. One small study in an electrophysiology lab demonstrated that the WCD could correctly identify and terminate most induced ventricular arrhythmias. A cohort study of WCD use estimated that the percent of successful resuscitations was approximately 70%. In that study, there was a high rate of nonadherence and dropouts, and failures to successfully resuscitate were largely attributed to incorrect use of the device and/or nonadherence. A more recent registry study reported high compliance rate when used as a trial for ICD implantation, though these results may be biased by self-selection. This evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice is likely to be inferior to a permanent ICD.

Pediatric Use

Despite the focus on WCD use in adults, a few studies have applied WCDs to pediatric populations, including patients between 9 and 17 years of age. One of the principle challenges with pediatric use is ensuring the appropriate WCD fitting around the torso of smaller children and adolescents. Collins et al retrospectively reviewed data of 81 patients ≤18 years of age (median age=16.5 [9-18]) and 103 patients
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19-21 years of age (median age=20 years). Both age groups exhibited an average compliance of 19 h/d (80% compliance). No appropriate therapy shocks occurred in patients ≤18 years of age, thus the study fails to address efficacy of the WCD for a pediatric population. Another study retrospectively analyzed WCD use of four pediatric patients with anthracycline-induced cardiomyopathy, two of which exhibited noncompliance with device wear. Two of the four patients required WCD downsizing to improve rhythm detection and electrode belt contact. These studies suggest WCDs can be an option for children at increased risk for SCD whose risks of ICD implantation outweigh the benefits; however, compliance and proper device fit remain challenges.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Cardiology, American Heart Association, et al

In 2016, the AHA issued specific recommendations regarding the use of WCDs for the prevention of SCD in a scientific advisory endorsed by the Heart Rhythm Society. The recommendations state:

- **Class IIa recommendations:**
  - “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 (Level of Evidence: C);”
  - “Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation (Level of Evidence: C).”

- **Class IIb recommendations:**
  - “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 diagnoses non-ischemic 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 (Level of Evidence: C).”
  - “WCDs may be appropriate as bridging therapy in situations 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 (Level of Evidence: C).”

- **Class III recommendations (no benefit):**
  - “WCDs should not be used when non-arrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months (Level of Evidence: C).”

The guidelines stress the importance of discussing patient preferences and addressing patient compliance, as patient discomfort and lifestyle concerns contribute to high discontinuation rates. The AHA highlights the need for prospective RCTs to provide comparative data.

In 2014, ACC and AHA issued guidelines on the management of non-ST-elevation acute coronary syndrome (NSTE-ACS). 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],”
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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.”

Expert Consensus Statement on ICD Therapy in Patients Not Well Represented in Clinical Trials

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. 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.”

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. 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).”

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.

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


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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<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>Update 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>September 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review, references 13, 20, 30-32 added. FDA regulatory status updated. Policy statements and guideline revised.</td>
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