FEP Medical Policy Manual

FEP 2.02.15 Wearable Cardioverter Defibrillators

Effective Policy Date: October 1, 2022

Original Policy Date: December 2011

Related Policies:

7.01.44 - Implantable Cardioverter Defibrillators

Wearable Cardioverter Defibrillators

Description

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, heart transplantation, or recovery.

POLICY STATEMENT

Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death may be considered **medically necessary** as interim treatment for those who:

- meet the criteria for an implantable cardioverter defibrillator (ICD; see indications in evidence review 7.01.44); 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:

- Individuals in the immediate (ie, <40 days) period following an acute myocardial infarction;
- Individuals post coronary artery bypass graft surgery;
- High-risk individuals awaiting heart transplant;
- Individuals 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 (ICD) placement. The most common reason will be a systemic infection that requires treatment before the ICD can be implanted. The wearable cardioverter defibrillator (WCD) should only be used short-term while the temporary contraindication (eg, systemic infection) is being clinically managed. Once treatment is completed, the permanent ICD 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 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."

In 2021, the FDA approved the ASSURE WCD for adult patients at risk for SCA who are not candidates for (or refuse) an ICD.

FDA product code: MVK.

RATIONALE

Summary of Evidence

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

One randomized controlled trial (RCT) has compared wearable cardioverter defibrillator (WCD) with usual guideline-based care and found no significant benefit to WCD over usual care. No studies have directly compared the performance of a WCD with a permanent implantable cardioverter defibrillator (ICD). One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. Similarly, a study of the ASSURE WCD in patients with cardiomyopathy found the WCD to detect all events recorded by an ICD with few false-positive shock alarms in a 30-day period. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice might be inferior to a permanent ICD.

Temporary Contraindications

For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies and a technology assessment that assessed ICD devices, given the absence of evidence on WCD devices. 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 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 an improvement in the net health outcome.

Immediate Post-Myocardial Infarction

For individuals who are in the immediate post-MI period who receive a WCD, the evidence includes a RCT comparing WCD with guideline-based therapy, 2 cohort studies, and a systematic review. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT reported no benefit of WCD over guideline-based therapy. The cohort study of 8453 patients showed that 252 shocks successfully terminated ventricular fibrillation (VF) or ventricular tachycardia (VT) (82% success rate), but without a control group, interpretation is difficult. Similarly, a retrospective cohort of Medicare data found that WCD use was associated with lower 1-year mortality than no WCD use, but potential biases were noted. Evidence from the systematic review was deemed of low to very low quality, and the reviewers had weak confidence in the reported estimates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Post - Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias

For individuals who are post -coronary artery bypass graft (CABG) surgery and are at high risk for lethal arrhythmias, the evidence includes an RCT for ICD and a registry study. 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. The registry study found survival benefits with WCD but had limited interpretation of data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias

For individuals who are awaiting heart transplantation and are at high risk for lethal arrhythmias, the evidence includes analyses of subsets of patients from the manufacturer registry, a subset from a prospective cohort study, and a case series. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. These studies do not provide sufficient evidence to determine whether a WCD is of benefit compared with usual care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Newly Diagnosed Nonischemic Cardiomyopathy

For individuals who have newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD and several retrospective analyses of WCD registry data. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that prophylactic ICD placement for nonischemic cardiomyopathy did not improve mortality compared with usual care. Evidence from the retrospective analysis was not sufficient to determine whether WCD improves outcomes compared with usual care. Given the lack of evidence that ICD improves outcomes, WCD is not expected to improve outcomes under the conditions studied in these trials. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Peripartum Cardiomyopathy

For individuals who have peripartum cardiomyopathy, the evidence includes a retrospective registry data analysis and a small cohort study. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The registry study revealed that no shocks were delivered during use over an average of 124 days. The cohort study identified 4 episodes of appropriate electric shock over 133 days. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association et al

In 2018, the American Heart Association (AHA), the American College of Cardiology, and the Heart Rhythm Society published a guideline on the management of patients with ventricular arrhythmias and prevention of SCD.[30,] 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 nonischemic cardiomyopathy, 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.

Level of evidence class IIa is moderate recommendation, class IIb is a weak recommendation, and class III is a moderate recommendation for no benefit or a strong recommendation for harm.

Table 1. Guidelines for WCD Therapy

Recommendation	COR	LOE[c]
"In patients with an ICD and a history of SCA or sustained ventricular arrhythmia in whom removal of the ICD is required (as with infection), the WCD is reasonable for the prevention of SCD."[a]	IIa	B-NR
"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 nonischemic cardiomyopathy, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the WCD may be reasonable."[b]	IIb	B-NR

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; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VT: ventricular tachycardia; 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 VT/SCD 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%.[31,] For patients with a history of SCA or sustained ventricular arrhythmia, the WCD may allow the patient to be discharged from the hospital with protection from VT/SCD 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 VT or SCD. 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.
[c] B-NR: data derived from ≥1 nonrandomized trials or meta-analysis of such studies.

In 2016, the AHA published a scientific advisory on the WCD.[32,] 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 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

Recommendation	COR	LOE[a]
"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."	IIa	C
"Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation."	IIa	C
"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."	IIb	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 days of MI."	IIb	C
"WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months."	III	C

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: *level of evidence*; MI: myocardial infarction; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.
[a] Level C evidence is based on limited data or expert opinion.

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.

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

Date	Action	Description
December 2011	New policy	
December 2012	Replace policy	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.
March 2014	Replace policy	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.
March 2015	Replace policy	Policy updated with literature review through November 30, 2014. References 17, 23, and 26-27 added. Investigational policy statements changed to not medically necessary.
September 2016	Replace policy	Policy updated with literature review, references 13, 20, 30-32 added. FDA regulatory status updated. Policy statements and guideline revised.
September 2018	Replace policy	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.
May 2019	Replace policy	Policy updated with literature review through March 4, 2019.; reference 31 added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through March 9, 2020; reference added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 10, 2021; reference added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through March 16, 2022; reference added. For standardization, wording of first policy statement revised as follows: "Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death may be considered medically necessary as interim treatment for those who:.." Other minor editorial policy statements refinements made with intent unchanged and policy statements otherwise unchanged.