BlueCross BlueShield of Alabama

Name of Policy:
Cardioverter Defibrillators: Wearable or External

Policy #: 557
Category: DME

Latest Review Date: June 2018
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure:

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.

Sudden Cardiac Arrest

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease.

Treatment

The ICD has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the 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 (MI) 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 events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See Policy No.168 "Cardioverter Defibrillators: Implantable" for further information on ICDs.

The WCD is an external device that is intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of a vest that is 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 that is 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.

Policy:

The **wearable cardioverter-defibrillator for the prevention of sudden cardiac death meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who meet **both** of the following criteria:

- meet the criteria for an implantable cardioverter-defibrillator (established by *medical policy* No.*168 Cardioverter Defibrillators: Implantable*); **AND**
- require interim treatment BUT cannot be treated with an implantable cardioverter defibrillator

And must also have one of the following criteria:

- Have a temporary contraindication to receiving an ICD such as a systemic infection, at the current time **and** has been scheduled for an ICD placement; **OR**
- Have a temporary contraindication to receiving an ICD such as a systemic infection, at the current time **and** had an ICD removed and has been rescheduled for placement of another ICD once the contraindication is treated.

The use of WCDs does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational for the following indications when they are the sole indication for a wearable cardioverter defibrillator:**

- Patients post coronary artery bypass graft surgery
- Patients with newly diagnosed nonischemic cardiomyopathy (excluding hypertrophic cardiomyopathy)
- Women with peripartum cardiomyopathy
- High-risk patients awaiting a heart transplant

The **wearable cardioverter-defibrillator for the prevention of sudden cardiac death meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who have had **a recent myocardial infarction and cannot be treated with an implantable cardioverter defibrillator until at least 40 days post MI**. This will be considered for up to 3 months.

The wearable cardiac defibrillator meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage **for 4 months** for patients with **hypertropic cardiomyopathy whose measured left ventricular ejection fraction is less than or equal to 35%**.

The use of WCDs does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational for all other indications.**

Automatic External Defibrillators (AEDs) for home use meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who **meet criteria for implantation of ICD**, **but cannot be treated with an implantable cardioverter defibrillator or have a contraindication to ICD placement**. Contraindications for ICD are the same as described in the previous paragraph under the wearable cardioverter-defibrillator.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update was conducted through March 14, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

FDA-labeled indications for the device are adult patients who are at risk for sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. These potential indications include:

- Bridge to transplantation (i.e., the WEARIT population)
- Bridge to implantable device or clinical improvement (i.e., the BIROAD population)
    - Postbypass with ejection fraction less than 30%
    - Postbypass with ventricular arrhythmias or syncope within 48 hours of surgery
    - Postmyocardial infarction with ejection fraction less than 30%
    - Postmyocardial 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

Overview of WCD vs ICD

The available evidence on the wearable cardioverter defibrillator (WCD) consists of case series describing outcomes from patients using the device. There are no RCTs comparing WCD with standard care or alternative treatments. RCTs of patients undergoing permanent implantable cardioverter defibrillator (ICD) placement can provide indirect evidence on the efficacy of the WCD if the (1) indications for a permanent ICD are similar to the indications for WCD and (2) performance of the WCD has been shown to approximate that of a permanent ICD. It was on

this basis that a TEC Assessment (2010) found that the evidence was sufficient to conclude that the WCD can successfully terminate malignant ventricular arrhythmias. Assessment conclusions were based on several factors. First, there is a 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 access placement and home use. Its novelty is in the way that the device is packaged and utilized. Second, some evidence has suggested 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 of 15 patients who were survivors of SCA and 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 nine of ten cases and successfully terminated the arrhythmia in all nine cases. In 2010, Chung et al published an evaluation of WCD effectiveness for preventing sudden death based on a postmarket release registry of 3,569 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.

Multiple studies have reported that adherence with WCD may be suboptimal. 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, two patients had four episodes of arrhythmia that were appropriately terminated by the WCD, one patient experienced two inappropriate treatments, and three patients experienced sudden death outside the hospital while not wearing their WCD device. Mitrani et al (2013) reported a dropout rate of 35% in a study of 134 consecutive, uninsured patients with cardiomyopathy and a mean ejection fraction (EF) of 22.5% who were prescribed a WCD. The WCD was never used by 8 patients, and 27% patients 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. Kao et al (2012) reported on the results of a prospective registry of 82 heart failure patients eligible for WCDs. Of these, 16% (n=13) did not wear the WCD due to refusal, discomfort, or other/unknown reasons. In the WEARIT and BIROAD studies (later combined), 2 unsuccessful defibrillations occurred in patients with incorrectly placed therapy electrodes (e.g., defibrillating pads reversed and not directed to the skin) with 1 SCD in a patient with reversed leads. These results suggested that the WCD might 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. However, high compliance with the WCD with a median daily use of 22.5 hours was reported in the WEARIT-II Registry, a large prospective study with 2000 patients from a real-world setting.

Section Summary: WCD vs ICD

There are no studies that directly compare the performance of a WCD with a permanent ICD. One small study in the electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. A cohort study of WCD use estimated that the percent 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 reported high compliance rate when used as a trial for ICD implantation, though 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 the overall performance in clinical care is likely to be inferior to a permanent ICD.

Temporary Contraindications to ICD

Contraindications to an ICD are few. According to the 1998 American College of Cardiology/American Heart Association (ACC/AHA) guidelines on ICD use, the device is contraindicated in patients with terminal illness, with drug-refractory class IV heart failure, who are not candidates for transplantation, and in patients with a history of psychiatric disorders that interfere with the necessary care and follow-up post-implantation. It is not known how many patients refuse an ICD after it has been recommended for them.

A subset of patients who may otherwise meet the established criteria for an ICD (see Policy No.168 Cardioverter Defibrillators: Implantable) but may have a temporary contraindication for an implantable device such as infection may benefit from WCD. Similarly, a patient with an existing ICD and concurrent infection may require explanation of the ICD may benefit this group during the time before reinsertion of ICD may be attempted.

Table 1. Key Nonrandomized Trial Characteristics Assessing Temporary Contraindications to an ICD

Study; Trial	Study Type	Country	Dates	Participants	Treatment	FU
Feldman et al (2004)[9]; WEARIT and BIROAD	Single-arm cohort	U.S.	2011-2014	Symptomatic NYHA functional class III or IV heart failure with LVEF <30% (WEARIT) or at high risk for SCD after MI or CABG surgery not receiving an ICD for up to 4 mo (BIROAD)	WCD	3.1 mo
Kutyifa et al (2015)[10]; WEARIT-II Registry	Prospective Registry	U.S., Germany	2011-2014	Post-MI with or without revascularization, new-onset dilated nonischemic cardiomyopathy or IHD or CHD	WCD	90 d

CABG: coronary artery bypass graft; CHD: congenital heart disease; FU: follow-up; ICD: implantable cardioverter defibrillator; IHD: inherited heart disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

Table 2. Key Nonrandomized Trial Results Assessing Temporary Contraindications to an ICD

Study; Trial	Appropriate Shock[a]	Inappropriate Shock[a]	Nonadherence
Feldman et al (2004)[9]; WEARIT and BIROAD	289	289	289

WCD, n/N (%)	6/8 (75%)	0.67 per month of use	6 sudden deaths: 5 not wearing; 1 incorrectly wearing the device
Kutyifa et al (2015)[10]; WEARIT-II Registry	2000		
WCD, n/N (%)	22/41 (54%)	10 (0.5%) patients	Not reported

ICD: implantable cardioverter defibrillator; WCD: wearable cardioverter defibrillator.
a Appropriate WCD therapy was classified as ventricular tachycardia or ventricular fibrillation episodes detected and treated by a WCD shock and inappropriate if not.

Section Summary: Temporary Contraindications to an ICD

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. Prospective cohort studies 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. These patients are expected to benefit from an ICD, and use of a WCD is a reasonable alternative because there are no other options for automatic detection and termination of ventricular arrhythmias.

Immediate Post-Myocardial Infarction Period

Evidence on the use of a WCD in the immediate post-MI period as a bridge to permanent ICD placement was reviewed in a 2010 TEC Assessment. For these patients, indications for a permanent ICD cannot be reliably assessed immediately post-MI because it is not possible to determine the final EF until at least 30 days after the event. Because the first 30 days after an acute MI represent a high-risk period for lethal ventricular arrhythmias, there is a potential to reduce mortality using other treatments to prevent SCA.

Two RCTs were specifically designed to address the question of early ICD use post-MI. The DINAMIT study evaluated the utility of an automatic ICD for this patient population. This trial randomly assigned 342 patients with an acute MI and an EF of 35% or less. The primary outcome was death from any cause, and a predefined secondary outcome was death from an arrhythmia. After a mean follow-up of 30 months, there was no difference in overall survival for the ICD group compared with control (HR=1.08; 95% CI, 0.76 to 1.55; p=0.66). There was a significant difference for the ICD group in the secondary outcome of death from arrhythmia (HR=0.42; 95% CI, 0.22 to 0.83; p=0.009). The decrease in deaths from arrhythmias for the ICD group was offset by a corresponding increase in deaths due to nonarrhythmic cardiac causes. The authors suggested that the discrepancy in these outcomes may have arisen from the fact that patients in whom the ICD successfully aborted an arrhythmia may have eventually died from other cardiac causes (e.g., progressive heart failure).

The IRIS trial was similar in design to the DINAMIT trial. This trial included 998 patients who were 5 to 31 days post-MI and had at least 1 other high-risk factor, either nonsustained VT or a resting pulse greater than 90. Patients were followed for a mean of 37 months. Results of the IRIS trial were similar to DINAMIT, with no difference in overall mortality between the ICD group (26.1%) and the control group (25.8%; p=0.76). The ICD group had a decreased rate of SCD (6.1% vs 13.2%, respectively, p=0.049), which was offset by a higher rate of non-SCD (15.3% vs 8.6%, respectively, p=0.001). This study also reported noncardiac death, which was similar for the ICD group (4.7%) and the control group (4.0%; p=0.51).

In 2013, Epstein et al reported on the results of a postmarket registry data from 8453 post-MI patients who received WCDs for risk of SCA while awaiting placement of an ICD. The WCD was worn a median length of 57 days (mean, 69 days) with a median daily use of 21.8 hours. Study characteristics and results are summarized in Tables 3 and 4, respectively. Appropriate shocks were delivered 309 times in 133 (1.6%) patients, 91% of which were successful in resuscitating patients from ventricular arrhythmias. For shocked patients, 62% were revascularized post-MI and the left ventricular ejection fraction (LVEF) averaged 23.8% (8.8%). While 1.4% of this registry population was successfully treated with WCDs, interpretation of registry data is limited.

Uyei and Braithwaite (2014) reported results of a systematic review conducted to evaluate the effectiveness of WCD use in several clinical situations, including individuals soon after post-MI (≤40 days) with a LVEF of 35% or less. Four studies (Chung et al [2010]], Epstein et al [2013], 2 conference abstracts) assessed the effectiveness of WCD use in post-MI patients. Outcomes reported were heterogeneous. For 2 studies that reported VF- and VT-related mortality, on average, 0.52% (2/384) of the study population died of VF or VT over a mean of 58.3 days of WCD use. For 2 studies that reported on VT and VF incidence, on average, 2.8% (11/384) of WCD users experienced a VT and/or VF event over a mean of 58.3 days of WD use (range, 3-146 days). Among those who experienced a VT or VF event, on average, 82% (9/11) had successful termination of 1 or more arrhythmic events.

The VEST trial (NCT00628966), which is testing the hypothesis that the WCD reduces sudden death mortality in the first 90 days after an MI in patients with reduced left ventricular function, is anticipated to reports its results in 2018 and will yield valuable prospective information on the proportion of patients who improve their LVEF more than 35% percent when receiving acute revascularization after MI.

Table 3. Key Nonrandomized Trial Characteristics in Immediate Post-MI Period

Study	Study Type	Country	Dates	Participants	Treatment	FU
Epstein et al (2013)	Retrospective registry (postmarket study)	U.S.	2005-2011	High-risk post-MI patients during the 40-d and 3-mo waiting periods	WCD	3 mo

FU: follow-up; MI: myocardial infarction; WCD: wearable cardioverter defibrillator.

Table 4. Key Nonrandomized Trial Results in Immediate Post Myocardial Infarction Period

Study	Outcomes
Epstein et al (2013)	N=8453
Wearable cardioverter defibrillator	• Number of patients receiving shock: 133 • Shock events: 146 • Appropriate shocks: 309 • Shocks successful in terminating VT or VF: 252 (82% success) • Shocks leading to asystole: 9 • Unsuccessful shocks: 41 (10% failure) • Inappropriate shocks: 99 patients received 114 inappropriate shocks

VF: ventricular fibrillation; VT: ventricular tachycardia.
a Shocks deemed appropriate if they occurred during sustained (>30 seconds) VT or VF and inappropriate if not.

Section Summary: Immediate Post-MI Period

Two RCTs of ICD use in the early post-acute MI period concluded that overall mortality did not differ when compared with usual care; however, the DINAMIT trial reported a significant decrease in the secondary outcome of death from arrhythmia and the IRIS trial reported a decreased rate of SCD.

Patients Post CABG Surgery Who Are at High Risk for Lethal Arrhythmias

Evidence on use of early ICD placement in high-risk post coronary artery bypass graft (CABG) patients with a low LVEF and abnormalities on signal-averaged electrocardiography consists of an RCT (CABG Patch) that reported no difference in overall mortality between the ICD and the control groups (HR=1.07; 95% CI, 0.81 to 1.42).

Zishiri et al (2013) reported on the results of a nonrandomized comparison of nearly 5000 patients with LVEF of 35% or less from 2 separate cohorts who underwent revascularization with CABG or percutaneous coronary intervention (809 patients discharged with a WCD from a national registry and 4149 patients discharged without WCD from Cleveland Clinic CABG and percutaneous coronary intervention registries). Study characteristics and results are summarized in Tables 5 and 6, respectively. Of the 809 patients treated with WCD, 1.3% had documented appropriate defibrillation treatment for an arrhythmia. Results show significant reduction in the mortality rates between the WCD group and the no WCD group. In this nonrandomized comparison, WCD use might have been associated with other confounding factors, including potential triggering of closer follow-up and reassessment for ICD implantation at subsequent follow-up. Therefore, use of WCD during this early period post-CABG should be evaluated in an RCT.

In the 2014 Uyei systematic review previously described, 3 studies (Chung et al, Epstein et al, 1 conference abstract) were identified that reported outcomes for WCDs after coronary revascularization for patients with LVEF of 35% or less. Reported outcomes were heterogeneous across studies. In 1 study that reported on VT/VF-related mortality, 0.41% (1/243) of the study population died of VT or VF over the course of 59.8 days (mean or median not specified). Of those who experienced a VT or VF event, 7% of patients died during "approximately 2 months" of WCD use. In another study, 50% of those with VT or VF events died over the course of 59.8 days. Reviewers concluded that the quality of evidence was low to very low quality and confidence in the reported estimates was weak.

Table 5. Key Nonrandomized Trial Characteristics in Patients Post-CABG Surgery at High Risk for Lethal Arrhythmias

Study	Study Type	Country	Dates	Participants	Treatment	Comparator	FU
Zishiri et al (2013)	Retrospective matched cohort	U.S.	2002-2009	Patients with low-EF post-PCI or post-ABG	WCD	No WCD	3.2 y

CABG: coronary artery bypass graft; EF: ejection fraction; FU: follow-up; PCI: percutaneous coronary intervention; WCD: wearable cardioverter defibrillator.

Table 6. Key Nonrandomized Trial Results in Patients Post-CABG Surgery at High Risk for Lethal Arrhythmias

Study	Post-CABG Mortality (90 Days)	Post-PCI Mortality (90 Days)	Post-CABG Mortality (Long Term)	Post-PCI Mortality (Long Term)
Zishiri et al (2013)				
WCD, n/N (%) (n=809)	7/26 (3.1%)	5/288 (1.7%)	19/226 (8.4%)	31/228 (11%)
No WCD, n/N (%) (4149)	135/2198 (6.1%)	189/1951 (9.7%)	636/2198 (29%	763/1951 (39%)
HR (95% CI); p			0.619 (0.385 to 0.997); adjusted p=0.048[a]	0.430 (0.290 to 0.638); <0.001[a]

CABG: coronary artery bypass graft; CI: confidence interval; HR: hazard ratio; PCI: percutaneous coronary intervention; WCD: wearable cardioverter defibrillator.
a Multivariable Cox proportional hazards analyses.

Section Summary: Patients Post CABG Surgery at High Risk for Lethal Arrhythmias
For high-risk post CABG patients, the evidence includes 1 RCT for ICD and a registry study for WCD. Analysis of data from the nonrandomized comparison using registry data found survival benefit with WCD but interpretation of registry data was limited. Because a permanent ICD does not appear to be beneficial in the early post-CABG period, a WCD would also not be beneficial for these patient populations.

Patients Awaiting Heart Transplantation Who Are High Risk for Lethal Arrhythmias
Many patients awaiting heart transplantation are at high risk for lethal arrhythmias and therefore ICD implantation is often recommended for such patients, particularly those discharged to home while awaiting transplantation. A WCD can be used to reduce risks associated with ICD implantation or in situations where an ICD is contraindicated.

In 2015, Opreanu et al analyzed a subset of patients prescribed a WCD as a bridge to heart transplantation from a retrospective analysis of a manufacturer's registry. Study characteristics and results are summarized in Tables 7 and 8, respectively. The registry included 121 patients, 12% with New York Heart Association (NYHA) functional class II heart failure, 32% with NYHA class III heart failure, 34% with NYHA class IV heart failure, and 21% unknown. Of the 121 patients, 73% were being evaluated for heart transplantation or were on a heart transplantation waiting list, and 27% were awaiting retransplantation following rejection of a prior heart transplantation. Patients wore the WCD for a median of 20 hours per day for a median of 39 days. Seven (6%) patients received appropriate WCD shocks during this period and survived. Two patients received inappropriate shocks. Thirteen (11%) patients ended WCD use after heart transplantation, 42% ended WCD use after ICD implantation, and 15% ended WCD use after EF improved. There were 11 (9%) deaths; 9 of these patients were not wearing a WCD at the time of death. The 2 patients who died while wearing the WCD had asystole.

Wässnig et al (2016) reported on the results of a national German registry of 6043 patients with multiple etiologies including dilated cardiomyopathy, myocarditis, and ischemic and nonischemic cardiomyopathies who were prescribed WCD. Study characteristics and results are

summarized in Tables 7 and 8, respectively. Overall, 1 (2.5%) of 40 patients awaiting heart transplantation was appropriately shocked for sustained VT or VF.

Table 7. Key Nonrandomized Trial Characteristics in Patients Awaiting HT at High Risk for Lethal Arrhythmias

Study	Study Type	Country	Dates	Participants	Treatment	FU
Opreanu et al (2015)	Retrospective registry	U.S.	2004-2011	Patients using the WCD for primary prevention of SCD in patients awaiting HT	WCD	39 d
Wässnig et al (2016)	Retrospective cohort	Germany, multiple sites	2010-2013	Patients with multiple etiology	WCD	NR

FU: follow-up; HT: heart transplant; NR: not reported; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

Table 8. Key Nonrandomized Trial Results in Patients Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias

Study	Appropriate Shock[a]	Inappropriate Shock[a]	Adherence
Opreanu et al (2015)			
WCD	7/121 (6%)	2/121 (2%)	Average of 20 h/d
Wässnig et al (2016)			
WCD	1/40 (2.5%)	Stratified data not reported	Stratified data not reported

WCD: wearable cardioverter defibrillator

Patients awaiting transplantation have also been included in studies with mixed populations. The combined WEARIT/BIROAD study (discussed previously) assessed a prospective cohort that included patients awaiting transplant, but it also included other high-risk patients and did not report separately on the population of patients awaiting transplant. Rao et al (2011) published a case series of 162 patients with congenital structural heart disease or inherited arrhythmias treated with WCD. Approximately one-third of these patients had a permanent ICD, which was explanted due to infection or malfunction. The remaining patients used the WCD either as a bridge to heart transplantation, during an ongoing cardiac evaluation, or in the setting of surgical or invasive procedures that increased the risk of arrhythmias. Four patients died during a mean duration of WCD treatment of approximately 1 month, but none was related to cardiac causes. Two patients received a total of 3 appropriate shocks for VT or VF, and 4 patients received a total of 7 inappropriate shocks. The results of this series suggested that the WCD can be worn safely and can detect arrhythmias in this population, but the rate of inappropriate shocks was relatively high.

Section Summary: Patients Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias

For patients awaiting hearth transplantation who are at high risk for lethal arrhythmias, evidence includes analyses of subsets of patients from manufacturer registry, a subset from a prospective cohort, and a case series. These studies do not provide sufficient evidence to determine whether a WCD improves outcomes compared with usual care.

Newly Diagnosed Nonischemic Cardiomyopathy

In patients with newly diagnosed nonischemic cardiomyopathy, final EF is uncertain because some patients show an improvement in EF over time.

The DEFINITE RCT compared ICD implantation plus standard medical therapy with standard medical therapy alone for primary prevention of SCD in patients who had nonischemic cardiomyopathy, nonsustained VT, and a LVEF of 35% or less. Results of this trial did not show a significant reduction in mortality with ICD regardless of duration since diagnosis (HR=0.65; 955 CI, 0.40 to 1.06; p=0.08). A post hoc analysis of the same trial by Kadish et al (2006) evaluated use of an ICD in patients with nonischemic dilated cardiomyopathy and examined the benefit of ICD use by time since diagnosis (<3 months and >9 months). This trial excluded patients with a clinical picture consistent with a reversible cause of cardiomyopathy and thus may differ from the population considered for a WCD. The difference in survival was of borderline significance for the ICD group compared with controls, both for the recently diagnosed subgroup (HR=0.38; 95% CI, 0.14 to 1.00; p=0.05) and the remotely diagnosed subgroup (HR=0.43; 95% CI, 0.22 to 0.99; p=0.046).

Study characteristics and results are summarized in Tables 9 and 10, respectively. In the WEARIT-II Registry study (discussed previously), 46% (n=927) of patients were prescribed WCD for nonischemic cardiomyopathy. After 3 months of follow-up, the rate of sustained VTs was 1% among those with nonischemic cardiomyopathy. However, outcomes data (appropriate and inappropriate shocks) were not reported separately for patients with nonischemic cardiomyopathy.

Another potential indication for the WCD is in in situations where the cardiomyopathy is reversible, but temporary protection against arrhythmias is needed. For example, this may occur in patients with alcoholic cardiomyopathy who abstain from alcohol. Salehi et al identified 127 patients from a manufacturer's database with nonischemic cardiomyopathy possibly related to alcohol use. Mean EF was 19.9% on presentation. Patients wore the WCD for a median of 51 days and a median of 18.0 hours a day. During this period, 7 patients received 9 appropriate shocks and 13 patients received 18 inappropriate shocks. At the end of WCD use, 33% of patients had improved EF and did not require ICD placement; 24% received an ICD. Four deaths occurred during this period, 1 while wearing the WCD (due to ventricular asystole).

Wässnig et al (2016) reported on the results of a national German registry of 6043 patients with multiple etiologies including dilated cardiomyopathy, myocarditis, and ischemic and nonischemic cardiomyopathies who were prescribed WCD. Overall 7 (1%) of 735 patients with nonischemic cardiomyopathy were appropriately shocked for sustained VT or VF.

Duncker et al (2017) reported on the results of the PROLONG study of 156 patients of whom 111 with nonischemic cardiomyopathy with a newly diagnosed LVEF of 35% or less were prescribed WCD and analyzed separately23 from the full cohort.

The 2014 Uyei systematic review (previously described) identified 4 studies (Saltzberg et al [2012], Chung et al [2010], 2 conference abstracts) that assessed WCD use in newly diagnosed nonischemic cardiomyopathy. In the 3 studies that reported VT and VF incidences, on average, 0.57% (5/871) subjects experienced VT and/or VF over a mean duration of 52.6 days. Among those who experienced a VT or VF event, on average, 80% had successful event termination.

Table 9. Key Nonrandomized Trial Characteristics for Newly Diagnosed Nonischemic Cardiomyopathy

Study; Trial	Study Type	Country	Dates	Participants	Treatment	FU
Kutyifa et al (2015); WEARIT-II Registry	Prospective registry	U.S., Germany	2011-2014	Patients with nonischemic cardiomyopathy	WCD	90 d
Salehi et al (2016)	Retrospective registry	U.S.	2005- 2012	Patients with nonischemic cardiomyopathy who self-reported a history of excess alcohol use	WCD	100 d
Duncker et al (2017); PROLONG	Retrospective cohort	Germany	2012- 2016	Newly diagnosed LVEF ≤35%	WCD	11 mo
Wässnig et al (2016)	Retrospective cohort	Germany, multiple sites	2010- 2013	Patients with multiple etiology	WCD	NR

FU: follow-up; LVEF: left ventricular ejection fraction; NR: not reported; WCD: wearable cardioverter defibrillator.

Table 10. Key Nonrandomized Trial Results for Newly Diagnosed Nonischemic Cardiomyopathy

Study; Trial	Appropriate Shock[a]	Inappropriate Shock[a]	Nonadherence
Kutyifa et al (2015); WEARIT-II Registry	927		
WCD	Not reported	Not reported	Not reported
Salehi et al (2016)			
WCD	7/127 (6%)	13/127 (10.2%)	
Duncker et al (2017); PROLONG			
WCD	8/117 (7%)	None	Of 156 (entire cohort), 48 terminated WCD treatment before 3-mo follow-up. Of the 48, 24 (50%) discontinued due to incompliance.
Wässnig et al (2016)[1]			
WCD	7/735 (1%)	Stratified data not reported	Stratified data not reported

WCD: wearable cardioverter defibrillator.

[a] Appropriate WCD therapy was classified as ventricular tachycardia or ventricular fibrillation episodes detected and treated by a WCD shock and inappropriate if not.

Section Summary: Newly Diagnosed Nonischemic Cardiomyopathy

For patients with newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD and multiple retrospective analyses of registry data for WCD. The RCT found that prophylactic ICD placement in nonischemic cardiomyopathy did not improve mortality compared with usual clinical care. The retrospective analysis did not provide sufficient evidence to determine whether a WCD improves outcomes compared with usual care. Thus, given the lack of evidence that a permanent ICD improves outcomes, a WCD is not expected to improve outcomes under the conditions studied in this trial.

Peripartum Cardiomyopathy

Saltzberg et al (2012) retrospectively analyzed a subset of 107 women with peripartum cardiomyopathy treated with a WCD device and compared with a matched sample of 159 nonpregnant women who had nonischemic dilated cardiomyopathy. The event rate was 0 in the

peripartum cardiomyopathy over an average of 124 days, compared with 2 shocks in 1 patient who had nonperipartum nonischemic cardiomyopathy over an average WCD use of 96 days..

In a smaller study reported in 2014, Duncker et al reported outcomes for 12 prospectively enrolled women with peripartum cardiomyopathy treated at a single center and followed for a median of 12 months. A WCD was recommended for 9 patients with LVEF of 35% or less, and 7 of them consented to wear the WCD. For these 7 patients, the median WCD wearing time was 81 days (mean, 133 days). In 3 patients, 4 episodes of VF were detected that led to delivery of a shock, which successfully terminated the arrhythmia in all cases. No inappropriate shocks were delivered. Among the 5 patients without WCD, no episodes of syncope or ventricular arrhythmia or deaths occurred.

Section Summary: Peripartum Cardiomyopathy

For peripartum cardiomyopathy, evidence includes a retrospective analysis of registry data registry and a small (N=7) case series. In the registry study of 107 patients, no shocks were delivered during use over an average of 124 days. The prospective cohort identified 4 episodes of appropriate electric shock during a mean 133 days. Additional study is needed to determine whether the WCD is effective in preventing SCD when used as a bridge to ICD placement or recovery in this population.

External Automatic Cardiac Defibrillators

Home use of an automatic external cardiac defibrillator is another potential alternative to either an ICD or a wearable defibrillator. However, there are no clinical trials that establish the efficacy of automatic external defibrillators for high-risk patients. Bardy et al randomly assigned 7,001 patients with anterior wall MI, who were not candidates for ICD implantation, to home external defibrillator or usual care. After a median follow-up of 37.3 months, there was no difference in mortality between groups (HR=0.97; 95% CI, 0.81 to 1.17).

Summary

Temporary Contraindications

For individuals who have a temporary contraindication for an implantable cardioverter defibrillator (ICD) who receive a wearable cardioverter defibrillator (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 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. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs reported a decrease in sudden cardiac death (SCD) in the ICD

group during the first 30 days post MI. However, there was an increase in non-SCD deaths from nonarrhythmic cardiac causes resulting in no net survival benefit. The evidence is sufficient 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 at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, 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. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment–related morbidity. For high-risk post coronary artery bypass graft patients, an RCT reported no difference in overall survival 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.

Practice Guidelines and Position Statements

American Heart Association and Heart Rhythm Society

In 2016, the American Heart Association (AHA) published a scientific advisory on the wearable cardioverter defibrillator (WCD). 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 11.

Table 11: Guidelines for WCD Therapy

Recommendation	COR	LOE
"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 situation 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."	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 mo."	III	C

AHA: American Heart Association; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: *level of evidence*; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

American College of Cardiology et al

The American College of Cardiology, AHA, and the Heart Rhythm Society jointly published guidelines on the management of adults who have ventricular arrhythmias or who are at risk for

sudden cardiac death, including diseases and syndromes associated with a risk of sudden cardiac death from ventricular arrhythmias. Recommendations related to the use of WCDs are provided in Table 12.

Table 12. Guidelines for WCD Therapy

Recommendations	COR	LOE
In patients with an implantable cardioverter defibrillator and a history of sudden cardiac arrest or sustained ventricular arrhythmia in whom removal of the implantable cardioverter defibrillator is required (as with infection), the wearable cardioverter defibrillator is reasonable for the prevention of sudden cardiac death.[a]	IIa	B-NR
In patients at an increased risk of sudden cardiac death but who are not ineligible for an implantable cardioverter defibrillator, 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, wearable cardioverter defibrillator may be reasonable.[b]	IIb	B-NR

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 cardia 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

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 [i.e., 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.

Key Words:

AICD, Wearable Cardioverter Defibrillator, Wearable Vest, LifeCor WCD System, LifeVest, Wearable Cardiac Defibrillator

Approved by Governing Bodies:

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001 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 and is now called 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."

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

93292	Interrogation device evaluation (in person) with physician analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745	Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

HCPC Codes:

E0617	External defibrillator with integrated electrocardiogram analysis
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

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Policy History:

Medical Policy Panel, January 2014
Medical Policy Group, July 2014 **(4):** Portions of the original policy 168 "Cardioverter Defibrillators: Implantable, Wearable, or External" were removed and placed on this policy (557) pertaining to the wearable and external defibrillators. No changes were made to the policy at this time. Key Points and References were updated.
Medical Review Committee, August 2014
Available for comment August 20 through October 3, 2014
Medical Policy Panel, January 2015
Medical Policy Group, January 2015 **(4):** Updates to Key Points and References. Policy statement rearranged to be more easily read. Policy statement intent unchanged.
Medical Policy Panel, May 2016

Medical Policy Group, June 2016 (**4**): Updates to Description, Key Points, Approved Governing Bodies, and References. Added policy statements to include investigational conditions for clarification. Policy intent unchanged.
Medical Policy Panel, May 2017
Medical Policy Group, June 2017 **(4):** Updates to Key Points and References. No change to policy statements.
Medical Policy Panel, May 2018
Medical Policy Group, June 2018 **(4):** Updates to Description, Key Points, and References. No change to policy statement.
Medical Policy Group, October 2018 (**4**): Clarification made to policy statement. No change in intent of statements.
