
Medical Policy



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(See policy history boxes for previous effective dates)

Title: Wearable Cardioverter Defibrillators

Description/Background

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.

Sudden Cardiac Arrest

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

Treatment

The implantable cardioverter defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of ICDs has been potentially 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 connect to a pulse generator implanted beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks.

The wearable cardioverter-defibrillator (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.

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

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

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

Regulatory Status

In 2001, The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via 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 and is now called the Zoll LifeVest®.

In 2015, the FDA approved the LifeVest® “for certain children who are at risk for sudden cardiac arrest but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent.”

Medical Policy Statement

The wearable cardioverter defibrillator is considered a temporary therapy for patients with a high risk for sudden cardiac death (SCD). A wearable cardioverter defibrillator is considered established when medical criteria is met.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

INCLUSIONS:

The wearable cardioverter defibrillator (WCDs) for the prevention of sudden cardiac death is considered established for the following conditions:

- Patients who meet qualifications for implantation of an ICD (*see Implantable Cardioverter Defibrillator(ICD), including Subcutaneous ICD policy criteria in Appendix 1), but because of the presence of a medical condition (e.g., localized skin/soft tissue infection at or near site of ICD implant, systemic infection), the implantation must be temporarily postponed, OR
- Patients who have an ICD which must be removed because of medical complication (e.g., infected ICD pocket, systemic infection), and must undergo a waiting period until the ICD can be replaced; OR
- Patients with familial or inherited conditions with a high risk of life-threatening ventricular tachycardia such as Long QT Syndrome or hypertrophic cardiomyopathy; OR
- Patients with a recent myocardial infarction (MI) or coronary revascularization with severely reduced left ventricular ejection fraction (LVEF <35%); OR
- Patients with newly diagnosed nonischemic cardiomyopathy with LVEF<35%; OR
- Patients who meet FDA criteria for this device.

EXCLUSIONS:

Wearable cardioverter defibrillators for all other indications.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

93292 93745 E0617 K0606 K0607 K0608

K0609

Other codes (investigational, not medically necessary, etc.):

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, 2 domains are examined: the relevance, and 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.

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

The available evidence on the wearable cardioverter defibrillator (WCD) consists of case series describing outcomes from patients using the device. There is 1 RCT comparing WCD with standard care. 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.³ 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. Auricchio et al (1998) reported on the first case series of 15 survivors of sudden cardiac arrest scheduled to receive an ICD.⁴ During the procedure to place 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 all 9 cases. Chunget al (2010) published an evaluation of WCD effectiveness in preventing sudden cardiac death (SCD) based on a postmarket release registry of 3569 patients who received a WCD.⁵ 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 and VF.

Multiple studies have reported that adherence with WCD may be suboptimal. Tanawuttiwat et al (2014) reported on the results of a retrospective, uncontrolled evaluation of 97 patients who received a WCD after their ICD was explanted due to device infection.⁶ 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 SCD 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.⁷ 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.⁸ Of these, 16% (n=13) did not wear the WCD due to refusal, discomfort, or other/unknown reasons. In the Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death (WEARIT) and Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months (BIROAD) studies (later combined), the 2 unsuccessful defibrillations occurred in patients with incorrectly placed therapy electrodes (e.g., defibrillating pads reversed and not directed to the skin) with one SCD in a patient with reversed leads.⁹ 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 Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients (WEARIT-II) Registry, a large prospective study with 2000 patients from a real-world setting.¹⁰

Section Summary: Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

One RCT compared 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 ICD. One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. 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.

Patients with Temporary Contraindication to an Implantable Cardioverter Defibrillator

Clinical Context and Therapy Purpose

The purpose of WCDs in patients who have risk of sudden death from cardiac arrest is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does a WCD improve the net health outcome?

The following PICOs were used to select literature to inform this review.

Populations

The relevant population of interest is patients at risk of death from cardiovascular arrest with a temporary contraindication to an implantable cardioverter defibrillator.

Interventions

The therapy being considered is a WCD.

Patients at risk for SCD are actively managed by cardiologists in an outpatient clinical setting.

Comparators

The following therapies are currently being used: usual clinical care.

Patients at risk for SCD are actively managed by cardiologists in an outpatient clinical setting.

Outcomes

The general outcomes of interest are survival over 10-year follow-up, heart attacks, function, and appropriate and inappropriate shocks from the WCD.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Contraindications to an ICD are few. According to the American College of Cardiology and American Heart Association(1998) guidelines on ICD use, the device is contraindicated in patients with terminal illness, in patients with drug-refractory class IV heart failure, in patients who are not candidates for transplantation, and in patients with a history of psychiatric disorders that interferes with the necessary care and follow-up postimplantation.¹¹ It is not known how many patients refuse an ICD placement after it has been recommended. A subset of patients who may otherwise meet the established criteria for an ICD (see evidence review 7.01.44) 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.

Study characteristics and results of 2 prospective cohort studies are summarized in Tables 1 and 2, respectively. The combined WEARIT and BIROAD study evaluated a prospective cohort of 289 patients at high-risk for SCD but who did not meet criteria for an ICD or who could not receive an ICD for several months.⁹ The WEARIT-II Registry study reported on the results of 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. 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 had improved.

Table 1. Key Nonrandomized Trial Characteristics Assessing Temporary Contraindications to an Implantable Cardioverter Defibrillator

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

BIROAD: Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months; 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. WEARIT: Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months.

Table 2. Key Nonrandomized Trial Results Assessing Temporary Contraindications to an Implantable Cardioverter Defibrillator

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

BIROAD: Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months; ICD: implantable cardioverter defibrillator; WCD: wearable cardioverter defibrillator. WEARIT: Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months.

^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: Patients with Temporary Contraindication to an Implantable Cardioverter Defibrillator

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.

Patients in Immediate Post Myocardial Infarction Period

Clinical Context and Therapy Purpose

The purpose of WCDs in patients who have risk of sudden death from cardiac arrest is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does a WCD improve the net health outcome in patients in the immediate post–myocardial infarction period?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients in the immediate post–myocardial infarction period.

Interventions

The therapy being considered is a WCD.

Patients at risk for SCD are actively managed by cardiologists in an outpatient clinical setting.

Comparators

The following therapies are currently being used: usual clinical care.

Patients at risk for SCD are actively managed by cardiologists in an outpatient clinical setting.

Outcomes

The general outcomes of interest are survival over 10-year follow-up, heart attacks, function, and appropriate and inappropriate shocks from the WCD.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Trial

Olgin et al (2018) randomly allocated 1524 patients with acute myocardial infarction and an ejection fraction $\leq 35\%$ to WCD and 778 to receive only guideline-based therapy (total N=2302).¹² Patients in the treatment group wore the device a median of 18.0 hours per day (interquartile range, 3.8 to 22.7). Within 90 days, 1.6% of participants in the WCD group and 2.4% of those in the control group had died of arrhythmia (relative risk [RR], 0.67; 95% CI, 0.37 to 1.21; $p=.18$). In the WCD group, death from any cause was seen in 3.1% of participants; in the control group, the death rate was 4.9% (RR, 0.64; 95% CI, 0.43 to 0.98; uncorrected $p=.04$). In the WCD group, of the 48 patients who died, 12 were wearing the WCD at time of death. Twenty participants in the WCD (1.3%) group received appropriate shock, and 9 (0.6%) an inappropriate shock. The results of the VEST trial (Vest Prevention of Early Sudden Death Trial)¹² demonstrated that the primary outcome of sudden death or death from ventricular tachyarrhythmia arrhythmic death) at 90 days, was not significantly lower among patients with a recent MI and an ejection fraction of 35% or less, when wearing the WCD. Patients were randomized to the device plus guideline-directed therapy ($n=1524$) or guideline-directed therapy only ($n=778$). Mean EF was 28% and 84% of participants had undergone revascularization (PCI) during the index hospitalization. The patients in the device group wore the device for a median of 18 hours a day (3.8-22.7). Death from arrhythmia occurred in 1.6% of the device group and 2.4% of those in the control group (relative risk, 0.67; 95% CI 0.37 to 1.21; $p=.18$).

Nonrandomized Trial

Epstein et al (2013) reported on the results of a post market registry data from 8453 post-MI patients who received WCDs for risk of sudden cardiac arrest while awaiting ICD placement.¹³ The WCD was worn a median 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. While 1.4% of this registry population was successfully treated with WCDs, interpretation of registry data is limited.

Uyei and Braithwaite (2014) reported on the 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.¹⁴ Four studies (Chung et al [2010],⁵ Epstein et al [2013],¹³ 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.

Table 3. Key Nonrandomized Trial Characteristics in Immediate Post–Myocardial Infarction Period

Study	Study Type	Country	Dates	Participants	Treatment	FU
Epstein et al (2013)	Retrospective registry (postmarket study)	United States	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	<ul style="list-style-type: none"> • Number of patients receiving shock: 133 • Shock events: 146 • Appropriate shocks^a: 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; WCD: wearable cardioverter defibrillator.

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

Section Summary: Patients in Immediate Post–Myocardial Infarction Period

One RCT of WCD in the early post-acute MI period found no benefit to WCD over guideline-directed therapy. Two RCTs of ICD use this period concluded that mortality rates did not improve compared with usual care. In both trials, SCD was reduced in the ICD group, but non-SCD events increased, resulting in no difference in overall mortality. Analysis of data from a retrospective post market registry reported a success rate of 82% but interpretation of registry data was limited in absence of a control group. The decision to prescribe the WCD in high-risk patients should be made by the treating physician and discussed with the patient to make a shared decision regarding their plan of care.

Patients with Newly Diagnosed Nonischemic Cardiomyopathy

Clinical Context and Therapy Purpose

The purpose of WCDs in patients who have risk of sudden death from cardiac arrest is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does a WCD improve the net health outcome in patients with newly diagnosed nonischemic cardiomyopathy?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with newly diagnosed nonischemic cardiomyopathy.

Interventions

The therapy being considered is a WCD.

Patients at risk for SCD are actively managed by cardiologists in an outpatient clinical setting.

Comparators

The following therapies are currently being used: usual clinical care.

Patients at risk for SCD are actively managed by cardiologists in an outpatient clinical setting.

Outcomes

The general outcomes of interest are survival over 10-year follow-up, heart attacks, function, and appropriate and inappropriate shocks from the WCD.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

In patients with newly diagnosed nonischemic cardiomyopathy, final EF is uncertain because some patients show an improvement in EF over time. The Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation RCT compared ICD implantation plus standard medical therapy with standard medical therapy alone for primary prevention of SCD in patients who had nonischemic cardiomyopathy, non-sustained 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; 95% CI, 0.40 to 1.06; p=.08). Kadish et al (2006) conducted a post hoc analysis of the same trial that 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).¹⁶ 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=.05) and the remotely diagnosed subgroup (HR=0.43; 95% CI, 0.22 to 0.99; p=.046).

Study characteristics and results are summarized in Tables 5 and 6, respectively. In the WEARIT-II Registry study (discussed previously), 46% (n=927) of patients were prescribed WCD for nonischemic cardiomyopathy.¹⁰ 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 alcoholic cardiomyopathy where cardiomyopathy is reversible but temporary protection against arrhythmias is needed. Salehi et al (2016) reported on the results of analysis of a subset of patients identified from manufacturer registry.¹⁷ 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. 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, with 1 death in a patient wearing 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.¹⁵ 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 Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator (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 separately¹⁸ from the full cohort.¹⁹

The Uyei and Braithwaite (2014) systematic review also identified 4 studies (Saltzberg et al [2012],¹⁴ Chung et al [2010],⁵ 2 conference abstracts) that assessed WCD use in newly diagnosed nonischemic cardiomyopathy.¹⁴ 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 5. 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	United States, Germany	2011-2014	Patients with nonischemic cardiomyopathy	WCD	90 d
Salehi et al (2016)	Retrospective registry	United States	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 6. 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 noncompliance.
Wässnig et al (2016)			
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: Patients with 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. The decision to prescribe the WCD in high-risk patients should be made by the treating physician and discussed with the patient to make a shared decision regarding their plan of care.

Summary of Evidence

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

One RCT has compared 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 ICD. One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. 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 can successfully deliver a countershock in most cases. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

Immediate Post Myocardial Infarction

For individuals who are in the immediate post myocardial infarction period who receive a WCD, the evidence includes a randomized controlled trial (RCT) comparing WCD with guideline-based therapy, a cohort study, 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 or ventricular tachycardia (82% success rate), but without a control group, interpretation is difficult. The American Heart Association et al (2018) has given a IIb recommendation for use of a Wearable Cardioverter-Defibrillator (WCD) for some patients who are less than 40 days from a myocardial infarction. The AHA determined that in some situations, a wearable cardioverter-defibrillator may be reasonable. The decision to prescribe the WCD in high-risk patients should be made by the treating physician and discussed with the patient to make a shared decision regarding their plan of care.

For bridging after myocardial infarction (MI), the data confirm the decrease in sudden cardiac arrest for those patients considered high-risk for ventricular arrhythmias. These patients may be receiving treatment for complications following an MI and have experienced VT/VF or cardiac arrest but are not yet candidates for a permanent implantable device.

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. The American Heart Association et al (2018) has given a IIb recommendation for use of a Wearable Cardioverter-Defibrillator (WCD) for patients newly diagnosed with non-ischemic cardiomyopathy. The AHA determined that in this situation, a wearable cardioverter-defibrillator may be reasonable. The decision to prescribe the WCD in high-risk patients should be made by the treating physician and discussed with the patient to make a shared decision regarding their plan of care.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

Position Statements

2014 Input

In response to requests, further input was received from 2 physician specialty societies and 7 academic medical centers while this policy was under review in 2014. Input related to the role of wearable cardioverter defibrillators (WCDs) in preventing sudden cardiac death among high-risk patients awaiting a heart transplant. Overall, input on the use of WCDs in this patient population was mixed. Some reviewers indicated that it may have a role among certain patients awaiting heart transplant, but there was no consensus on specific patient indications for use. 2013 Input

In response to requests, input was received from 3 physician specialty societies and 8 academic medical centers while this policy was under review in 2013. Overall, the input was mixed. Most, but not all, providing comments suggested that the WCD may have a role in select high-risk patients following acute myocardial infarction or in newly diagnosed cardiomyopathy. However, reviewers acknowledged the lack of evidence for benefit and consistency in the evidence in defining high-risk subgroups that may benefit.

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 sudden cardiac death.²⁰ 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 non-ischemic cardiomyopathy (NICM), recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT/SCA.

Table 7. AHA et al Guidelines for Wearable Cardioverter Defibrillator Therapy

Recommendation	COR	LOE
"In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD."	Ila	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 NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable."	Ilb	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; NICM: non-ischemic cardiomyopathy; SCA: sudden cardiac arrest; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

American Heart Association

In 2016, the AHA published a scientific advisory on the WCD.²¹ 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 8.

Table 8. AHA Guidelines for Wearable Cardioverter Defibrillator 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."	Ila	C
"Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation"	Ila	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."	Ilb	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."	Ilb	C

U.S. Preventive Services Task Force Recommendations

Not applicable.

Government Regulations

National:

There is no National Coverage determination on this topic.

Local:

There is a Local Coverage Determination (L33690), "Automatic External Defibrillators" Effective for services performed on or after 10/01/2015; Revised 01/01/20

Automatic external defibrillators are covered for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described under I or II. It is expected the treating practitioner be experienced in the management of beneficiaries at risk for SCD.

- I. A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the criteria (1-4), described below:
 1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; or 1.
 2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or 2.
 3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or 3. 4.
 4. A previously implanted defibrillator now requires explantation

- II. A nonwearable automatic defibrillator (E0617) is covered for beneficiaries in two circumstances. They meet either (1) both criteria A and B or (2) criteria C, described below:
 - A. The beneficiary has one of the following conditions (1-8):
 1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause.
 2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause
 3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy
 4. Coronary artery disease with a documented prior myocardial infarction with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;

- a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
 - b. The EP test must have been performed more than 4 weeks after the qualifying myocardial.
5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30. Beneficiaries must not have:
 - a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or,
 - b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or,
 - c. Had an enzyme-positive MI within past month; or,
 - d. Clinical symptoms or findings that would make them a candidate for coronary revascularization.
 - e. Irreversible brain damage from preexisting cerebral disease; or,
 - f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
 6. Beneficiaries with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure and measured left ventricular ejection fraction (LVEF) \leq 35%.
 7. Beneficiaries with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF \leq 35%
 8. Beneficiaries who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure

B. Implantation surgery is contraindicated

C. A previously implanted defibrillator now requires explantation

Additional Medicare Guidelines and pre-requirements available (L33690)

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33690&ver=20&bc=CAAAAAAAAAAAAA>

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Implantable Cardioverter Defibrillator(ICD), including Subcutaneous ICD

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 24, 2022, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/21	2/16/21		Joint policy established
5/1/22	2/15/22		Routine maintenance

Next Review Date: 1st Qtr, 2023

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: WEARABLE CARDIOVERTER DEFIBRILLATORS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate, and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.

APPENDIX 1

From the ICD, including Subcutaneous ICDs policy Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Standard automatic implantable cardioverter defibrillators

I. Adults

The use of the automatic implantable cardioverter defibrillator (ICD) may be considered **established** in adults who meet the following criteria:

Primary Prevention

Inclusions:

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less; or
 - Ischemic cardiomyopathy with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; or
 - Nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; 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 non-sustained 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.
 - 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
 - Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death
 - Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest, if meaningful survival of greater than 1 year is expected;
 - LVEF 35% or less, despite optimal medical therapy and a period of immunosuppression (if there is active inflammation), if meaningful survival of greater than 1 year is expected;
 - LVEF greater than 35%, if meaningful survival of greater than 1 year is expected;
- AND
- syncope or near-syncope, felt to be arrhythmic in etiology OR
 - evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan OR
 - Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant VF

- An indication for permanent pacemaker implantation.

Exclusions:

The use of the ICD is considered experimental/**investigational** in primary prevention patients who:

- Have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment);
- Have New York Heart Association (NYHA) class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device);
- Have had a cardiac revascularization procedure in past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; or
- Have noncardiac disease that would be associated with life expectancy less than 1 year.

Secondary Prevention

Inclusions:

- 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.

Exclusions:

- The use of the ICD is considered experimental/**investigational** for all other indications.

II. Pediatrics

Inclusions:

The use of the ICD or SCD may be considered **established** in children who meet any of the following criteria:

- Survivors of cardiac arrest, after reversible causes have been excluded;
- Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or
- Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.
- Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history or premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; massive left ventricular hypertrophy based on age-specific norms; 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
- 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.

Exclusions:

The use of the ICD is considered **experimental/investigational** for all other indications in pediatric patients.