Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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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 connected to a pulse generator placed beneath the skin of the chest or abdomen. Placement of the ICD 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; and
- Patients who refuse device therapy.

It is uncommon for individuals 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.”

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

FDA product code: MVK.

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

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

- Individuals who meet qualifications for implantation of an ICD (*see Implantable Cardioverter Defibrillator (ICD), including Subcutaneous ICD and Substernal ICDs 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

- Individuals 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

- Individuals with familial or inherited conditions with a high risk of life-threatening ventricular tachycardia such as Long QT Syndrome or hypertrophic cardiomyopathy; OR

- Individuals with a recent myocardial infarction (MI) or coronary revascularization with severely reduced left ventricular ejection fraction (LVEF <35%); OR

- Individuals with newly diagnosed nonischemic cardiomyopathy with LVEF<35%; OR

- Individuals 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.):

N/A

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

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.

Goetz et al (2023) published a systematic review of the only available RCT (n=2348) and 11 observational studies (n=5345) in patients that used a WCD to prevent SCD.[26] Data from the RCT was not pooled with data from the observational studies. Indications for WCDs varied among the observational studies and follow-up ranged from 6 weeks to 36.2 months. Compliance in the observational studies ranged from 20 to 23.5 hours per day. The rate of appropriate and inappropriate shocks was 1% to 4.8% and 1% to 2%, respectively. The analysis was limited by a high risk of bias in 8 of the 11 observational studies and a low or very low certainty of evidence among the included studies.

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 Investigative Trial (WEARIT) and Bridge to ICD in Patients at Risk of Arrhythmic Death (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 1 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]

In a 2022 study of the ASSURE WCD device, 130 patients with ICD were fitted with the WCD and followed for 30 days. [11] The WCD was enabled for detection and shock alarms were recorded; however, shocks and shock alarms were disabled on the WCD. The study was conducted at multiple centers in the US, and enrolled patients had cardiomyopathy of various etiologies. The majority of the patients were male (≈70%) and white (≈64%). The WCD detected 163 events with 3 false-positive shock alarms (0.00075 false-positive shock alarms per patient-day). No events recorded by the ICD were missed by the WCD. Adherence was good with median wear of 31 days and median daily use of 23 hours. Although adherence in

this study appears improved compared with studies of other devices, the short duration and small sample size limit applicability.

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. Similarly, a study of the ASSURE WCD in patients with cardiomyopathy found the WCD to detect all events recorded by an ICD with few false-positive shock alarms in a 30-day period. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately70%. 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 individuals 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 following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is a WCD.

Comparators

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

Outcomes

The general outcomes of interest are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. Specific outcomes of interest include survival over 10-year follow-up, myocardial infarction (MI) , 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.[12] 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; a WCD 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: Bridge to ICD in Patients at Risk of Arrhythmic Death ; CABG: coronary artery bypass graft; CHD: congenital heart disease; IHD: inherited heart disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; SCD: sudden cardiac death; WEARIT: Wearable Defibrillator Investigative Trial ; WEARIT-II: Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients; WCD: wearable cardioverter defibrillator.

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: Bridge to ICD in Patients at Risk of Arrhythmic Death; WEARIT: Wearable Defibrillator Investigative Trial ; WEARIT-II: Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients; 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 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 individuals 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 following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is a WCD.

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 overall survival, morbid events, functional outcomes, and treatment-related morbidity. Specific outcomes of interest include survival over 10-year follow-up, MI , 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

Use of WCD in the immediate post-MI period as a bridge to permanent ICD placement was reviewed in a TEC Assessment (2010).[3] 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. Despite the rationale for this potential indication, the TEC Assessment concluded that the available evidence does not support the contention that any cardioverter defibrillator improves mortality in patients in the immediate post-MI period. Two RCTs (Defibrillator in Acute Myocardial Infarction Trial [DINAMIT] and Immediate Risk Stratification Improves Survival [IRIS]) and a post hoc analysis of an RCT, the Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction (MADIT-II) led to this conclusion. In the DINAMIT (674 patients) and IRIS (898 patients) trials, which randomized patients with LVEF of 35% or less to early ICD implantation 6 to 40 days after acute MI or medical therapy alone, there was no significant improvement in overall mortality.[13,14] The hazard ratios (HR) for OS in the DINAMIT and IRIS trials were 1.08 (95% confidence interval [CI], 0.76 to 1.55; p=.66) and 1.04 (95% CI, 0.81 to 1.35; p=.78), respectively. Despite a reduction in arrhythmic deaths among patients with an ICD, there was a higher risk of non-arrhythmic deaths during this early period, resulting in similar overall mortality rates in the 2 trials. Secondary analysis of data from the MADIT-II trial showed that the survival benefit associated with ICDs appeared to be greater for remote MI and remained substantial for up to 15 or more years after MI. Within the first 18 months post-MI, there was no benefit found for ICD placement (HR, 0.97; 95% CI, 0.51 to 1.81; p=.92). In contrast, there was a significant mortality benefit when the length of time since MI was greater than 18 months (HR, 0.55; 95% CI, 0.39 to 0.78; p=.001).

Olgin et al (2018) randomly allocated patients with an acute MI and an EF of 35% or less to either WCD (n=1524) or to receive only guideline-based therapy (n=778).[15] 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 this trial show that for patients with these specific conditions, the WCD did not improve the rate of arrhythmic death compared with usual care.

Nonrandomized Trial

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 post-MI (≤40 days) with a left ventricular ejection fraction (LVEF) of 35% or less.[16] Four studies (Chung et al [2010];[5], Epstein et al [2013], described in detail below;[17,] and 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 WCD use (range, 3 to 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. Reviewers concluded that the quality of evidence was low to very low quality and confidence in the reported estimates was weak.

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.[17] 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.

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

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[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 in 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 the 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 individuals 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 following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is a WCD.

Comparators

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

Outcomes

The general outcomes of interest are overall survival, morbid events, functional outcomes, and treatment-related morbidity. Specific outcomes of interest include survival over 10-year follow-up, MI, 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
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 inpatients 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; 955 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).[18] 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).

Nonrandomized Trial
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 VT 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.[19] 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.[20] 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 separately[20] from the full cohort.[21]

The Uyei and Braithwaite (2014) systematic review also identified 4 studies (Saltzberg et al [2012],[23] Chung et al[2010],[5] 2 conference abstracts) that assessed WCD use in newly diagnosed nonischemic cardiomyopathy.[16] 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 analyses 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 randomized controlled trial (RCT) has compared wearable cardioverter defibrillators (WCDs) with usual guideline-based care and found no significant benefit to WCD over usual care. No studies have directly compared the performance of a WCD with a permanent implantable cardioverter defibrillator (ICD). One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. Similarly, a study of the ASSURE WCD in patients with cardiomyopathy found that the WCD detected all events recorded by an ICD with few false-positive shock alarms in a 30-day period. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice might be inferior to a permanent ICD.

Temporary Contraindications
For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies and a technology assessment that assessed ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. The available data have established that the WCD device can detect lethal arrhythmias and successfully deliver a countershock in most cases. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Immediate Post-Myocardial Infarction
For individuals who are in the immediate post myocardial infarction (MI) 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 (VF) or ventricular tachycardia (VT) (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.[24] 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 [ventricular tachycardia/sudden cardiac arrest].

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

Table 7. 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."	IIa	B-NR
"In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable."	IIb	B-NR

B-NR: Level B - nonrandomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VT: ventricular tachycardia; WCD: wearable cardioverter defibrillator. [a] Removal of an ICD for a period of time, most commonly due to infection, exposes the patient to risk of untreated VT/SCD unless monitoring and access to emergency external defibrillation is maintained. In 1 series of 354 patients who received the WCD, the indication was infection in 10%.[31] For patients with a history of SCA or sustained ventricular arrhythmia, the WCD may allow the patient to be discharged from the hospital with protection from VT/SCD until the clinical situation allows reimplantation of an ICD. [b] The patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the WCD. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT or SCD. However, the WCD is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time. In patients awaiting transplant, even with anticipated survival <1 year without transplant, and depending on clinical factors such as use of intravenous inotropes and ambient ventricular arrhythmia, a WCD may be an alternative to an ICD. [c] B-NR: data derived from ≥1 nonrandomized trials or meta-analysis of such studies.

American Heart Association

In 2016, the AHA published a scientific advisory on the WCD.[25] 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 [U.S. Food and Drug Administration]-approved indications for use." The specific recommendations are summarized in Table 8.

Table 8. 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."	IIa	C
"Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation"	IIa	C
"Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction/ for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable."	IIb	C

"WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 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

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) ≤ 35%.
7. Beneficiaries with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF ≤ 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=CAAAAAAAAAAA

(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 ICDs and Substernal ICDs

References

1. Food and Drug Administration. Summary of Safety and Effectiveness Data, P010030, Lifecor, Inc. WCD 2000System. 2001; https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030b.pdf. Accessed April 21, 2021.
2. Beauregard LA. Personal security: Clinical applications of the wearable defibrillator. Pacing Clin Electrophysiol. Jan2004; 27(1): 1-3. PMID 14720147
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Wearable cardioverter-defibrillator as a bridge to implantable cardioverter-defibrillator treatment. TEC Assessments. 2010;Volume 25:Tab 2.
4. Auricchio A, Klein H, Geller CJ, et al. Clinical efficacy of the wearable cardioverter-defibrillator in acutely terminating episodes of ventricular fibrillation. Am J Cardiol. May 15 1998; 81(10): 1253-6. PMID 9604964
5. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. J Am Coll Cardiol. Jul 13 2010; 56(3): 194-203. PMID 20620738
6. Tanawuttiwat T, Garisto JD, Salow A, et al. Protection from outpatient sudden cardiac death following ICD removal using a wearable cardioverter defibrillator. Pacing Clin Electrophysiol. May 2014; 37(5): 562-8. PMID 24762055
7. Mitrani RD, McArdle A, Slane M, et al. Wearable defibrillators in uninsured patients with newly diagnosed cardiomyopathy or recent revascularization in a community medical center. Am Heart J. Mar 2013; 165(3): 386-92.PMID 23453108
8. Kao AC, Krause SW, Handa R, et al. Wearable defibrillator use in heart failure (WIF): results of a prospective registry. BMC Cardiovasc Disord. Dec 12 2012; 12: 123. PMID 23234574
9. Feldman AM, Klein H, Tchou P, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. Pacing Clin Electrophysiol. Jan 2004; 27(1): 4-9. PMID14720148.
10. Kutyifa V, Moss AJ, 10. Klein H, et al. Use of the wearable cardioverter defibrillator in high-risk cardiac patients: data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry).Circulation. Oct 27 2015; 132(17): 1613-9. PMID 26316618
11. Poole JE, Gleva MJ, Birgersdotter-Green U, et al. A wearable cardioverter defibrillator with a low false alarm rate. J Cardiovasc Electrophysiol. Feb 16 2022. PMID 35174572
12. Gregoratos G, Cheitlin MD, Conill A, et al. ACC/AHA guidelines for implantation of cardiac pacemakers and anti-arrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). J Am Coll Cardiol. Apr 1998; 31(5): 1175-209. PMID9562026
13. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. Dec 09 2004; 351(24): 2481-8. PMID 15590950
14. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. Oct 08 2009; 361(15): 1427-36. PMID 19812399
15. Olgin JE, Pletcher MJ, Vittinghoff E, et al. Wearable Cardioverter-Defibrillator after Myocardial Infarction. N Engl J Med. Sep 27 2018; 379(13): 1205-1215. PMID 30280654
16. Uyei J, Braithwaite RS. Effectiveness of wearable defibrillators: systematic review and quality of evidence. Int J Technol Assess Health Care. Apr 2014; 30(2): 194-202. PMID 24893969

17. Epstein AE, Abraham WT, Bianco NR, et al. Wearable cardioverter-defibrillator use in patients perceived to be at high risk early post-myocardial infarction. J Am Coll Cardiol. Nov 19 2013; 62(21): 2000-2007. PMID 23916930
18. Kadish A, Schaechter A, Subacius H, et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. J Am Coll Cardiol. Jun 20 2006; 47(12): 2477-82. PMID 16781376
19. Salehi N, Nasiri M, Bianco NR, et al. The Wearable Cardioverter Defibrillator in Nonischemic Cardiomyopathy: A US National Database Analysis. Can J Cardiol. Oct 2016; 32(10): 1247.e1-1247.e6. PMID 26975224
20. Wassnig NK, Gunther M, Quick S, et al. Experience with the Wearable Cardioverter-Defibrillator in Patients at High Risk for Sudden Cardiac Death. Circulation. Aug 30 2016; 134(9): 635-43. PMID 27458236
21. Duncker D, Konig T, Hohmann S, et al. Ventricular arrhythmias in patients with newly diagnosed nonischemic cardiomyopathy: Insights from the PROLONG study. Clin Cardiol. Aug 2017; 40(8): 586-590. PMID 28333373
22. Duncker D, Konig T, Hohmann S, et al. Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator-The PROLONG Study. J Am Heart Assoc. Jan 17 2017; 6(1). PMID 28096098
23. Saltzberg MT, Szymkiewicz S, Bianco NR. Characteristics and outcomes of peripartum versus nonperipartum cardiomyopathy in women using a wearable cardiac defibrillator. J Card Fail. Jan 2012; 18(1): 21-7. PMID 22196837
24. Al-Khatib SM, Stevenson WG, Ackerman MJ et al. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice guidelines and the Heart Rhythm society. J Am Cardiol 2018; 138(13): e272:e391. PMID 29084731
25. Piccini, JP Sr, Allen LA, Kudenchuk PJ, et al. Wearable Cardioverter -Defibrillator Therapy for the Prevention of Sudden Cardiac Death, A Science Advisory From the American Heart Association. Circulation 2016; 133:1722. PMID 27022063
26. Goetz G, Wernly B, Wild C. Wearable cardioverter defibrillator for preventing sudden cardiac death in patients at risk: An updated systematic review of comparative effectiveness and safety. Int J Cardiol Heart Vasc. Apr 2023; 45: 101189. PMID 37025482

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through December 30, 2024, 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
5/1/23	2/21/23		Routine maintenance. Vendor Review: NA (ky)
5/1/24	2/20/24		Routine maintenance. Vendor Review: NA (ky)
5/1/25	2/18/25		Routine maintenance. Vendor Review: NA (ky)

Next Review Date: 1st Qtr, 2026

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 and Substernal ICDs policy Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration)

Transvenous 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 individuals 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;
        - Left ventricular ejection fraction (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.

*Criteria for ICD implantation in individuals with cardiac ion channelopathies:
Individuals with cardiac ion channelopathies may have a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes, in which case they should be considered for ICD implantation for secondary prevention, even if they do not meet criteria for primary prevention.

Criteria for ICD placement in individuals with cardiac ion channelopathies derive from results of clinical input, a 2013 consensus statement from the HRS, European Heart Rhythm Association (EHRA), and the Asia-Pacific Heart Rhythm Society on the diagnosis and management of individuals with inherited primary arrhythmia syndromes, and a report from the HRS and EHRA's Second Consensus Conference on Brugada syndrome.

Indications for consideration for ICD placement for each cardiac ion channelopathy are as follows:

- Long QT syndrome (LQTS):
  - Individuals with a diagnosis of LQTS who are survivors of cardiac arrest
  - Individuals with a diagnosis of LQTS who experience recurrent syncopal events while on β-blocker therapy.
- Brugada syndrome (BrS):
  - Individuals with a diagnosis of BrS who are survivors of cardiac arrest
  - Individuals with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope
  - Individuals with a spontaneous diagnostic type 1 electrocardiogram (ECG) who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out)
  - Individuals with a diagnosis of BrS who develop ventricular fibrillation during programmed electrical stimulation.
- Catecholaminergic polymorphic ventricular tachycardia (CPVT):
  - Individuals with a diagnosis of CPVT who are survivors of cardiac arrest
  - Individuals with a diagnosis of CPVT who experience recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation.
- Short QT syndrome (SQTS):
  - Individuals with a diagnosis of SQTS who are survivors of cardiac arrest
  - Individuals with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope
  - Individuals with a diagnosis of SQTS who are asymptomatic or symptomatic and have a family history of sudden cardiac death.

NOTE: For congenital LQTS, individuals may have 1 or more clinical or historical findings other than those outlined above that could, alone or in combination, put them at higher risk for sudden cardiac death. They can include individuals with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, individuals with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and individuals with a diagnosis of LQTS with

profound QT prolongation (>550 ms). These factors should be evaluated on an individualized basis by a clinician with expertise in LQTS when considering the need for ICD placement.

Exclusions:
The use of the ICD is considered experimental/**investigational** in primary prevention individuals 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.
- The use of the ICD for primary prevention is considered experimental/investigational for all other indications not meeting criteria.

Secondary Prevention
Inclusions:

- Individuals 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 for secondary prevention is considered experimental/**investigational** for all other indications not meeting criteria.

II. Pediatrics

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

- Survivors of cardiac arrest, after reversible causes have been excluded; **or**
- Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in individuals 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; **or**
- 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; **or**
- Diagnosis of any one of the following cardiac ion channelopathies*(please refer to Criteria for ICD implantation in individuals with cardiac ion channelopathies above) 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 transvenous ICD is considered **experimental/investigational** for all other indications in pediatric patients that do not meet the criteria.

Subcutaneous automatic implantable cardioverter defibrillators
The use of a subcutaneous ICD may be considered **established** for adult or pediatric individuals who have an indication for Transvenous ICD implantation for primary or secondary prevention for any of the above reasons and meet **all** of the following criteria:

- Have a contraindication to a transvenous ICD due to 1 or more of the following: (1) lack of adequate vascular access; (2) compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger individual with anticipated long-term need for ICD therapy); or (3) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy;
- Have no indication for antibradycardia pacing;
- Do not have ventricular arrhythmias known or anticipated to respond to antitachycardia pacing;
- A high risk for infection, e.g., immunocompromised patients or those with a history of a previous transvenous infection
- History of congenital heart disease with anatomic limitations for transvenous placement of the transvenous AICD
- History of need for explantation of a tranvenous ICD due to a complication, with ongoing need for ICD therapy

Exclusions:

- The individual has a need for cardiac pacing
- The use of subcutaneous ICD for all other indications that do not meet the above criteria.

Substernal implantable cardioverter defibrillator
The substernal ICD is experimental/investigational for all indications.