2.02.15	Wearable Cardioverter Defibrillators		
Original Policy Date:	December 7, 2006	Effective Date:	July 1, 2023
Section:	2.0 Medicine	Page:	Page 1 of 26

Policy Statement

I. Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death may be considered **medically necessary** as interim "bridge" treatment for a period not to exceed 90 days, when **all** of the following are met:
   A. The patient does NOT have New York Heart Association (NYHA) class IV congestive heart failure that is refractory to optimal medical management (and cannot undergo cardiac transplantation)
   B. The patient does NOT have a live expectancy of less than 1 year
   C. Documentation of **one or more** of the following:
      1. Patient in the period immediately following an acute myocardial infarction (<40 days), whose ejection fraction is equal to or less than 35%
      2. Patient is less than 3 months post coronary artery bypass graft (CABG) surgery and whose ejection fraction is equal to or less than 35%
      3. Patient with newly diagnosed nonischemic cardiomyopathy when **ALL** of the following:
         a. Reversible cause of left ventricular dysfunction not yet maximally treated
         b. Ejection fraction is equal to or less than 35%
      4. High-risk patient awaiting heart transplant (renewable every three months for this indication)
      5. Women with peripartum cardiomyopathy
      6. Use of an ICD is planned but the patient has a temporary contraindication (e.g., systemic or local infection, lack of vascular access, etc.) or had and ICD removed with a plan for replacement after the contraindication is treated or is no longer a problem

II. Use of WCDs is considered **investigational** for all other indications, including use in members who are otherwise terminal from any cause, or with New York Heart Association (NYHA) Class IV congestive heart failure patients who are refractory to optimal medication treatment and who cannot undergo cardiac transplantation.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Certain medical conditions listed below may pose an added risk of lethal arrhythmia until natural cardiac remodeling (healing) occurs, which ultimately eliminates the risk of arrhythmia and the need for a permanent ICD. Use of wearable cardioverter defibrillators (WCDs) for the interim prevention of sudden cardiac death while this healing occurs is proposed but remains incompletely proven and is under active investigation for these conditions when they are the sole indication for a WCD. However, to allow for the potential anti-arrhythmic benefit the WCD may be considered medically necessary for a period not to exceed 90 days for:

- Patients in the period immediately following an acute myocardial infarction, whose ejection fraction is equal to or less than 35%
- Patients post coronary artery bypass graft (CABG) surgery whose ejection fraction is equal to or less than 35%
- Patients with newly diagnosed nonischemic cardiomyopathy (without a reversible cause of left ventricular dysfunction) whose ejection fraction is equal to or less than 35%
- High-risk patients awaiting heart transplant (renewable every three months for this indication)

- Women with peripartum cardiomyopathy

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

Coding

The following CPT code describes the professional services involved in the initial setup and programming of this device:

- 93745: Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

The following CPT code describes interrogation of a wearable cardioverter defibrillator device:

- 93292: Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system*

*Code 93292 cannot be reported with code 93745.

A wearable cardioverter defibrillator (HCPCS code K0606) is a rental DME (durable medical equipment) device only. The rental allowance includes all necessary equipment, delivery, set-up, maintenance, and repair costs:

- K0606: Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

The following HCPCS codes represent replacement supplies and accessories for use with K0606; however, these supplies are inclusive in the rental of the wearable cardioverter defibrillator (K0606):

- K0607: Replacement battery for automated external defibrillator, garment type only, each
- K0608: Replacement garment for use with automated external defibrillator, each
- K0609: Replacement electrodes for use with automated external defibrillator, garment type only, each

Description

A wearable cardioverter defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter defibrillator (ICD). It is primarily intended for temporary conditions for which an implantable device is contraindicated, or for the period during which the need for a permanent implantable device is uncertain.

Related Policies

- Implantable Cardioverter Defibrillators

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2001, the Lifecor WCD® 2000 system was approved by the FDA through the premarket approval process for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The vest was renamed the LifeVest®.

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

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

FDA product code: MVK.

Rationale

Background
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, use of ICDs has been broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction (EF).

Implantable cardioverter defibrillators 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 events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See Blue Shield of California Medical Policy: Implantable Cardioverter Defibrillators for further information on ICDs.

The wearable cardioverter defibrillator (WCD) is an external device intended to perform the same tasks as an ICD, without invasive procedures. It consists of a vest 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 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 who 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 Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death [WEARIT] study population)
- Bridge to implantable device or clinical improvement (i.e., the Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months [BIROAD] study population)
    - Post bypass with EF less than 30%
    - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
    - Post MI with EF less than 30%
    - Post MI with ventricular arrhythmias within 48 hours
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a 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 to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

There is 1 RCT comparing wearable cardioverter defibrillator (WCD) with standard care. Randomized controlled trials 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 (SCA) 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. Chung et 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 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 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 a 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 following PICO was 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 ICD.

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 explantation 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 ICD

Trial	Study Type	Country	Dates	Participants	Treatment	Follow-up
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 months (BIROAD)	WCD	3.1 months
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 days

BIROAD: Bridge to ICD in Patients at Risk of Arrhythmic Death ; CABG: coronary artery bypass graft; CHD: congenital heart disease; 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; 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 ICD

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 ; ICD: implantable cardioverter defibrillator; 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 a 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 following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients in the immediate post-MI period.

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 OS, 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 nonarrhythmic 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 postmarket registry data from 8453 post-MI patients who received WCDs for risk of SCA 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. It is not possible to determine whether outcomes were improved without a control group, and the registry contained limited patient and medical information, making interpretation of results difficult.

Clark et al (2019) reported on the results of a retrospective cohort analysis of Medicare claims data of 16,935 patients who were post-MI and received WCDs.[18,] The analysis utilized a 5% sample of Medicare's Standard Analytical Files (2010 to 2012) and included patients with an inpatient admission for acute MI. One-year adjusted mortality rates were compared between patients who received a WCD within 15 days of discharge and those who did not receive a WCD (Tables 3 and 4). The 30-day mortality rate in the WCD group was not reported due to Medicare restrictions on reporting that represents less than 11 beneficiaries, but was stated to be lower than that in the no WCD group (10.4%; p=.18). While these results favored WCD, interpretation of these findings is limited; for example, the authors noted the potential for confounding by indication and performance bias, and the WCD group was significantly younger and had more frequent congestive heart failure, unstable angina and other acute ischemic heart disease.

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

Study	Study Type	Country	Dates	Participants	Treatment	Follow-up
Epstein et al (2013)[17,]	Retrospective registry (postmarket study)	United States	2005-2011	High-risk post-MI patients during the 40-day and 3-month waiting periods	WCD	3 months
Clark et al (2019)[18,]	Retrospective cohort	United States	2010-2012	Medicare patients hospitalized for MI	WCD	1 year

MI: myocardial infarction; WCD: wearable cardioverter defibrillator.

Table 4. Key Nonrandomized Trial Results in Immediate Post-MI Period

Study	Outcomes
Epstein et al (2013)[17,]	N=8453
WCD	• Number of patients receiving shock: n=133 • Shock events: n=146 • Appropriate shocksa: n=309 • Shocks successful in terminating VT or VF: n=252 (82% success) • Shocks leading to asystole: n=9 • Unsuccessful shocks: n=41 (10% failure) • Inappropriate shocks: n=99 patients received 114 inappropriate shocks
Clark et al (2019)[18,]	N=16,935
WCD, n/N (%) (n=89)	1-year mortality: NR (11.5%)
No WCD, n/N (%) (n=16,846)	1-year mortality: NR (19.8%)
HR (95% CI)	1-year mortality 0.46 (NR)

CI: confidence interval; HR: hazard ratio; NR: not reported; 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 postmarket registry reported a success rate of 82% but interpretation of registry data was limited in the absence of a control group. Similarly, a retrospective cohort of Medicare data found that WCD use was associated with lower 1-year mortality than no WCD use, but potential biases were noted. Because a permanent ICD does not appear to be beneficial in the early post-MI period, a WCD would also not be beneficial for these patient populations.

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

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

Populations

The relevant population of interest is patients post-coronary artery bypass graft (CABG) surgery who are at high risk for lethal arrhythmias.

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 OS, 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
Evidence on use of early ICD placement in high-risk post-CABG patients with a low LVEF and abnormalities on signal-averaged electrocardiography consists of an RCT (CABG Patch) that reported no difference in overall mortality between the ICD and the control groups (HR, 1.07; 95% CI, 0.81 to 1.42).[19,]

Nonrandomized Trial
Zishiri et al (2013) reported on the results of a nonrandomized comparison of nearly 5000 patients with LVEF of 35% or less from 2 separate cohorts who underwent revascularization with CABG or percutaneous coronary intervention (809 patients discharged with a WCD from a national registry and 4149 patients discharged without WCD from Cleveland Clinic CABG and percutaneous coronary intervention registries).[20,] Study characteristics and results are summarized in Tables 5 and 6, respectively. Results show significant reduction in the mortality rates between the WCD group and the no WCD group. In this nonrandomized comparison, WCD use might have been associated with other confounding factors, including potential triggering of closer follow-up and reassessment for ICD implantation at subsequent follow-up. Therefore, use of WCD during this early period post-CABG should be evaluated in an RCT.

In the Uyei and Braithwaite (2014) systematic review (previously described), 3 studies (Chung et al (2010),[5,] Epstein et al (2014),[17,]and 1 conference abstract) were identified; they reported outcomes for WCDs after coronary revascularization for patients with a LVEF of 35% or less.[16,] Reported outcomes were heterogeneous across studies. In 1 study that reported on VT- and VF-related mortality, 0.41% (1/243) of the study population died of VT or VF over 59.8 days (mean or median not specified). Of those who experienced a VT or VF event, 7% of patients died during "approximately 2 months" of WCD use. In another study, 50% of those with VT or VF events died over 59.8 days. Reviewers concluded that the quality of evidence was low to very low quality and confidence in the reported estimates was weak.

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

Study	Study Type	Country	Dates	Participants	Treatment	Comparator	Follow-up
Zishiri et al (2013)[20,]	Retrospective matched cohort	United States	2002-2009	Patients with low EF post-percutaneous coronary intervention or post-CABG	WCD	No WCD	3.2 years

CABG: coronary artery bypass graft; EF: ejection fraction; WCD: wearable cardioverter defibrillator.

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

Study	Post-CABG Mortality (90 Days)	Post-Percutaneous Coronary Intervention Mortality (90 Days)	Post-CABG Mortality (Long-Term)	Post-Percutaneous Coronary Intervention Mortality (Long-Term)
Zishiri et al (2013)[20],				
WCD, n/N (%) (N=809)	7/26 (3.1%)	5/288 (1.7%)	19/226 (8.4%)	31/228 (11%)
No WCD, n/N (%) (N=4149)	135/2198 (6.1%)	189/1951 (9.7%)	636/2198 (29%)	763/1951 (39%)
HR (95% CI); p			0.619 (0.385 to 0.997); adjusted p=.048[a]	0.430 (0.290 to 0.638); <.001[a]

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

Section Summary: Patients Post–Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias

For high-risk post-CABG patients, the evidence includes an RCT for ICD and a registry study for WCD. The RCT reported no difference in OS associated with early ICD placement. Analysis of data from the nonrandomized comparison using registry data found survival benefit with WCD but interpretation of registry data was limited. Because a permanent ICD does not appear to be beneficial in the early post-CABG period, a WCD would also not be beneficial for these patient populations.

Patients Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias

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

Populations

The relevant population of interest is patients awaiting heart transplantation at high risk for lethal arrhythmias.

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 OS, 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

Many patients awaiting heart transplantation are at high risk for lethal arrhythmias, and therefore ICD implantation is often recommended for such patients, particularly those discharged to home while awaiting transplantation. A WCD can be used to reduce risks associated with ICD placement or when ICD placement is contraindicated.

Opreanu et al (2015) analyzed a subset of patients prescribed a WCD as a bridge therapy to heart transplant from a retrospective analysis of a manufacturer's registry.[21,] Study characteristics and results are summarized in Tables 7 and 8, respectively. Thirteen (11%) patients ended WCD use after heart transplantation, 42% ended WCD use after ICD placement, and 15% ended WCD use after EF improved. There were 11 (9%) deaths; 9 of them were not wearing a WCD at the time of death. The 2 patients who died while wearing the WCD had an 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.[22,] Study characteristics and results are summarized in Tables 7 and 8, respectively. Overall, 1 (2.5%) of 40 patients awaiting heart transplantation was appropriately shocked for sustained VT or VF.

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

Study	Study Type	Country	Dates	Participants	Treatment	Follow-up
Opreanu et al (2015)[21,]	Retrospective registry	U.S.	2004-2011	Patients using the WCD for primary prevention of SCD in patients awaiting heart transplantation	WCD	39 days
Wässnig et al (2016)[22,]	Retrospective cohort	Germany, multiple sites	2010-2013	Patients with multiple etiology	WCD	NR

NR: not reported; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

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

Study	Appropriate Shock[a]	Inappropriate Shock[a]	Adherence
Opreanu et al (2015)[21,]			
WCD	7/121 (6%)	2/121 (2%)	Average of 20 hours/day
Wässnig et al (2016)[22,]			
WCD	1/40 (2.5%)	Stratified data not reported	Stratified data not reported

WCD: wearable cardioverter defibrillator.
[a] A WCD shock was considered appropriate if delivered for sustained ventricular arrhythmias and inappropriate if occurring for arrhythmias other than sustained ventricular arrhythmia.

Patients awaiting transplantation have also participated in studies with mixed populations. The combined WEARIT and BIROAD study (discussed previously) assessed a prospective cohort that included patients awaiting transplant and other high-risk patients; it did not report data separately for the population awaiting transplant.[9,] Rao et al (2011) published a case series of 162 patients with congenital structural heart disease or inherited arrhythmias treated with WCD.[23,] Approximately one-third of these patients had a permanent ICD, which was explanted due to infection or malfunction. The remaining patients used the WCD either as a bridge to heart transplantation, during an ongoing cardiac evaluation, or in the setting of surgical or invasive procedures that increased the risk of arrhythmias. Four patients died during a mean WCD treatment duration of approximately 1 month, but none was related to cardiac causes. Two patients received 3 appropriate shocks for VT or VF, and 4 patients received 7 inappropriate shocks. The results of this series suggested that the WCD can be worn safely and can detect arrhythmias in this population, but the rate of inappropriate shocks was relatively high.

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

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

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 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.

Comparators

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

Outcomes

The general outcomes of interest are OS, 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 in patients who had nonischemic cardiomyopathy, nonsustained VT, and a LVEF of 35% or less. Results of this trial did not show a significant reduction in mortality with ICD regardless of duration since diagnosis (HR, 0.65; 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).[24,] 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 9 and 10, respectively.

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.[25] Mean EF was 19.9% on presentation. Patients wore the WCD for a median of 51 days and a median of 18.0 hours per 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.[22] 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[26] from the full cohort.[27]

The Uyei and Braithwaite (2014) systematic review also identified 4 studies (Saltzberg et al [2012],[28] Chung et al [2010],[5] and 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 9. Key Nonrandomized Trial Characteristics for Newly Diagnosed Nonischemic Cardiomyopathy

Study; Trial	Study Type	Country	Dates	Participants	Treatment	Follow-up
Kutyifa et al (2015)[10]; WEARIT-II Registry	Prospective registry	U.S. , Germany	2011-2014	Patients with nonischemic cardiomyopathy	WCD	90 days
Salehi et al (2016)[25]	Retrospective registry	U.S.	2005-2012	Patients with nonischemic cardiomyopathy who self-reported a history of excess alcohol use	WCD	100 days
Duncker et al (2017)[26,27]; PROLONG	Retrospective cohort	Germany	2012-2016	Newly diagnosed LVEF ≤35%	WCD	11 months
Wässnig et al (2016)[22]	Retrospective cohort	Germany, multiple sites	2010-2013	Patients with multiple etiology	WCD	NR

LVEF: left ventricular ejection fraction; NR: not reported; PROLONG: Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator; WEARIT-II: Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients; WCD: wearable cardioverter defibrillator.

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

Study; Trial	Appropriate Shock[a]	Inappropriate Shock[a]	Nonadherence
Kutyifa et al (2015)[10]; WEARIT-II Registry	927		
WCD	Not reported	Not reported	Not reported

Study; Trial	Appropriate Shock[a]	Inappropriate Shock[a]	Nonadherence
Salehi et al (2016)[25,]			
WCD	7/127 (6%)	13/127 (10.2%)	
Duncker et al (2017)[26,27,]; PROLONG			
WCD	8/117 (7%)	None	Of 156 (entire cohort), 48 terminated WCD treatment before 3-month follow-up. Of the 48, 24 (50%) discontinued due to noncompliance.
Wässnig et al (2016)[22,]			
WCD	7/735 (1%)	Stratified data not reported	Stratified data not reported

PROLONG: Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator; 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 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 s did not provide sufficient evidence to determine whether a WCD improves outcomes compared with usual care. Thus, given the lack of evidence that a permanent ICD improves outcomes, a WCD is not expected to improve outcomes under the conditions studied in this trial.

Patients With Peripartum 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 following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with peripartum 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 OS, 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

Saltzberg et al (2012) retrospectively analyzed a subset of 107 women with peripartum cardiomyopathy treated with a WCD device and compared with a matched sample of 159 nonpregnant women who had nonischemic dilated cardiomyopathy.[28,] The event rate was 0 in the peripartum cardiomyopathy group over an average WCD use of 124 days, compared with 2 shocks in 1 patient who had nonperipartum nonischemic cardiomyopathy over an average WCD use of 96 days.

Dunker et al (2014) reported on outcomes for 12 prospectively enrolled women with peripartum cardiomyopathy treated at a single center and followed for a median of 12 months.[29,] A WCD was recommended for 9 patients with a LVEF of 35% or less and 7 of them consented to wear the WCD. For these 7 patients, median WCD wearing time was 81 days (mean, 133 days). In 3 patients, 4 episodes of VF were detected that led to delivery of a shock, which successfully terminated the arrhythmia in all cases. No inappropriate shocks were delivered. Among the 5 patients without WCD, no episodes of syncope or ventricular arrhythmia or deaths occurred.

Section Summary: Patients With Peripartum Cardiomyopathy

For peripartum cardiomyopathy, evidence includes a retrospective analysis of registry data and a small case series (N=7). In the registry study of 107 patients, no shocks were delivered during use over an average of 124 days. The prospective cohort identified 4 episodes of appropriate electric shock during a mean 133 days. Thus, given the lack of evidence that a permanent ICD improves outcomes, a WCD is not expected to improve outcomes under the conditions studied in this trial.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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 (SCD) 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 (MI) 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.

Practice Guidelines and Position Statements

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

American Heart Association et al

In 2018, the American Heart Association (AHA), the American College of Cardiology, and the Heart Rhythm Society published a guideline on the management of patients with ventricular arrhythmias and prevention of SCD.[30] The guidelines note that "the patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the wearable cardioverter-defibrillator. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT/SCA [ventricular tachycardia/sudden cardiac arrest]. However, the wearable cardioverter-defibrillator is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time." The specific recommendations are summarized in Table 11. 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 11. Guidelines for WCD Therapy

Recommendation	COR	LOE[c]
"In patients with an ICD and a history of SCA or sustained ventricular arrhythmia in whom removal of the ICD is required (as with infection), the WCD is reasonable for the prevention of SCD."[a]	IIa	B-NR
"In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed nonischemic cardiomyopathy, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the WCD may be reasonable."[b]	IIb	B-NR

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

In 2016, the AHA published a scientific advisory on the WCD.[32] The AHA stated that "because there is a paucity of prospective data supporting the use of the WCD, particularly in the absence of any published, randomized, clinical trials, the recommendations provided in this advisory are not intended to be prescriptive or to suggest an evidence-based approach to the management of patients with FDA [U.S. Food and Drug Administration]-approved indications for use." The specific recommendations are summarized in Table 12.

Table 12. Guidelines for WCD Therapy

Recommendation	COR	LOE[a]
"Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection."	IIa	C
"Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation."	IIa	C
"Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction/ for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable."	IIb	C
"WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI."	IIb	C
"WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months."	III	C

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 13.

Table 13. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05201495[a]	A Clinical Evaluation of the Jewel P-WCD in Subjects at High Risk for Sudden Cardiac Arrest	290	Jun 2023
NCT02816047	Indications for and Experience With the Wearable Cardioverter Defibrillator (WCD)–Austrian WCD Registry	450	Mar 2022
	EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry[b]		
NCT05135403[a]	ASSURE WCD Clinical Evaluation - Post Approval Study (ACE-PAS)	5179	Feb 2025

NCT: national clinical trial.
[a] Denotes industry sponsored or co-sponsored study.
[b] Available at: https://www.escardio.org/Research/Registries-&-surveys/Observational-research-programme/PeriPartum-CardioMyopathy-PPCM-Registry.

References

1. Food and Drug Administration. Summary of Safety and Effectiveness Data, P010030, Lifecor, Inc. WCD 2000 System. 2001; https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030b.pdf. Accessed March 14, 2023.
2. Beauregard LA. Personal security: Clinical applications of the wearable defibrillator. Pacing Clin Electrophysiol. Jan 2004; 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. PMID 14720148
10. Kutyifa V, Moss AJ, 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. May 2022; 33(5): 831-842. PMID 35174572
12. Gregoratos G, Cheitlin MD, Conill A, et al. ACC/AHA guidelines for implantation of cardiac pacemakers and antiarrhythmia 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. PMID 9562026
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. Clark MA, Szymkiewicz SJ, Volosin K. Mortality and Costs Associated with Wearable Cardioverter-defibrillators after Acute Myocardial Infarction: A Retrospective Cohort Analysis of Medicare Claims Data. J Innov Card Rhythm Manag. Oct 2019; 10(10): 3866-3873. PMID 32477706
19. Bigger JT. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. N Engl J Med. Nov 27 1997; 337(22): 1569-75. PMID 9371853
20. Zishiri ET, Williams S, Cronin EM, et al. Early risk of mortality after coronary artery revascularization in patients with left ventricular dysfunction and potential role of the wearable cardioverter defibrillator. Circ Arrhythm Electrophysiol. Feb 2013; 6(1): 117-28. PMID 23275233
21. Opreanu M, Wan C, Singh V, et al. Wearable cardioverter-defibrillator as a bridge to cardiac transplantation: A national database analysis. J Heart Lung Transplant. Oct 2015; 34(10): 1305-9. PMID 26094085

22. Wäßnig NK, Günther 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
23. Rao M, Goldenberg I, Moss AJ, et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. Am J Cardiol. Dec 01 2011; 108(11): 1632-8. PMID 21890075
24. 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
25. 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
26. Duncker D, König 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
27. Duncker D, König 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
28. 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
29. Duncker D, Haghikia A, König T, et al. Risk for ventricular fibrillation in peripartum cardiomyopathy with severely reduced left ventricular function-value of the wearable cardioverter/defibrillator. Eur J Heart Fail. Dec 2014; 16(12): 1331-6. PMID 25371320
30. 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. Circulation. Sep 25 2018; 138(13): e272-e391. PMID 29084731
31. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). Pacing Clin Electrophysiol. Mar 2010; 33(3): 353-67. PMID 19889186
32. Piccini JP, 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. Apr 26 2016; 133(17): 1715-27. PMID 27022063

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or cardiology consultation report including:
  - Clinical justification for a Wearable Cardioverter Defibrillator
  - Documentation specifying temporary contraindication to receiving an ICD if applicable (e.g., a systemic infection at the current time, lack of vascular access, recent myocardial infarction with low ejection fraction, etc.)
  - Past cardiac surgical history (e.g., ICD placement or explantation, revascularization procedures) and dates associated (if applicable)
  - Specific documentation required to meet ICD criteria (when applicable):
    - Cardiac monitoring result(s) (e.g., EKG, Holter, hemodynamic or EP studies, echocardiogram)
    - Clinical justification for ICD placement
    - Date ICD procedure is planned and type of ICD requested (automatic or subcutaneous)
    - Estimated life expectancy based on medical history (non-cardiac)

  - Family history of sudden cardiac death (including generation)
  - Left ventricular ejection fraction and date obtained
  - Major risk factors for sudden cardiac death
  - Myocardial infarction history including date
  - NYHA Functional Classification
  - Past medical treatment and response(s)
- Echocardiogram report within the past six months

For a renewal or extension (in addition to the above, please include the following):

- Reason for extension and duration of need
- Office notes for the past 4 months, including plan of care
- Recent applicable test results (e.g., echocardiogram)
- Anticipated time to implanting an ICD or stopping the use of a wearable cardioverter defibrillator

Post Service (in addition to the above, please include the following):

- Operative procedure report(s) relating to an ICD (if applicable)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
	93745	Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events
HCPCS	E0617	External defibrillator with integrated electrocardiogram analysis
	K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
	K0607	Replacement battery for automated external defibrillator, garment type only, each
	K0608	Replacement garment for use with automated external defibrillator, each
	K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/07/2006	BCBSA Medical Policy adoption
09/25/2009	Criteria Revised Policy title change. Prior Policy title: Wearable Cardioverter-Defibrillators for the Prevention of Sudden Cardiac Death
01/11/2013	Policy revision without position change
07/14/2014	Policy title change from Wearable Cardioverter Defibrillator Policy revision with position change
05/29/2015	Policy title change from Wearable Cardioverter-Defibrillators Policy revision without position change
01/01/2017	Policy revision with position change
07/01/2017	Policy revision without position change
09/01/2018	Policy revision without position change
07/01/2019	Policy revision without position change
06/01/2020	Administrative update. Policy statement and guidelines updated.
07/01/2020	Annual review. No change to policy statement. Literature review updated.
08/01/2020	Policy statement, guidelines and literature review updated.
07/01/2021	Annual review. No change to policy statement. Literature review updated.
07/01/2022	Annual review. No change to policy statement. Policy guidelines and literature updated.
07/01/2023	Annual review. No change to policy statement. Policy guidelines and literature updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
Wearable Cardioverter Defibrillators 2.02.15 Policy Statement: I. Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death may be considered **medically necessary** as interim "bridge" treatment for a period not to exceed 90 days, when **all** of the following are met: A. The patient does NOT have New York Heart Association (NYHA) class IV congestive heart failure that is refractory to optimal medical management (and cannot undergo cardiac transplantation) B. The patient does NOT have a live expectancy of less than 1 year C. Documentation of **one or more** of the following: 1. Patient in the period immediately following an acute myocardial infarction (<40 days), whose ejection fraction is equal to or less than 35% 2. Patient is less than 3 months post coronary artery bypass graft (CABG) surgery and whose ejection fraction is equal to or less than 35% 3. Patient with newly diagnosed nonischemic cardiomyopathy when **ALL** of the following: a. Reversible cause of left ventricular dysfunction not yet maximally treated b. Ejection fraction is equal to or less than 35% 4. High-risk patient awaiting heart transplant (renewable every three months for this indication) 5. Women with peripartum cardiomyopathy 6. Use of an ICD is planned but the patient has a temporary contraindication (e.g., systemic or local infection, lack of vascular access, etc.) or had and ICD removed with a plan for replacement after the contraindication is treated or is no longer a problem	Wearable Cardioverter Defibrillators 2.02.15 Policy Statement: I. Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death may be considered **medically necessary** as interim "bridge" treatment for a period not to exceed 90 days, when **all** of the following are met: A. The patient does NOT have New York Heart Association (NYHA) class IV congestive heart failure that is refractory to optimal medical management (and cannot undergo cardiac transplantation) B. The patient does NOT have a live expectancy of less than 1 year C. Documentation of **one or more** of the following: 1. Patient in the period immediately following an acute myocardial infarction (<40 days), whose ejection fraction is equal to or less than 35% 2. Patient is less than 3 months post coronary artery bypass graft (CABG) surgery and whose ejection fraction is equal to or less than 35% 3. Patient with newly diagnosed nonischemic cardiomyopathy when **ALL** of the following: a. Reversible cause of left ventricular dysfunction not yet maximally treated b. Ejection fraction is equal to or less than 35% 4. High-risk patient awaiting heart transplant (renewable every three months for this indication) 5. Women with peripartum cardiomyopathy 6. Use of an ICD is planned but the patient has a temporary contraindication (e.g., systemic or local infection, lack of vascular access, etc.) or had and ICD removed with a plan for replacement after the contraindication is treated or is no longer a problem

POLICY STATEMENT (No changes)	
BEFORE	AFTER
II. Use of WCDs is considered **investigational** for all other indications, including use in members who are otherwise terminal from any cause, or with New York Heart Association (NYHA) Class IV congestive heart failure patients who are refractory to optimal medication treatment and who cannot undergo cardiac transplantation.	II. Use of WCDs is considered **investigational** for all other indications, including use in members who are otherwise terminal from any cause, or with New York Heart Association (NYHA) Class IV congestive heart failure patients who are refractory to optimal medication treatment and who cannot undergo cardiac transplantation.