Medical Policy

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Title: Wearable Cardioverter Defibrillators

Related Policies:	▪ *Implantable Cardioverter Defibrillators*

Professional / Institutional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With a temporary contraindication to an implantable cardioverter defibrillator	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • Who are in the immediate post myocardial infarction period	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes

Populations	Interventions	Comparators	Outcomes
			• Treatment-related morbidity
Individuals: • Who are post coronary artery bypass graft surgery and are at high risk for lethal arrhythmias	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • Who are awaiting heart transplantation and are at high risk for lethal arrhythmias	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With newly diagnosed nonischemic cardiomyopathy	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With peripartum cardiomyopathy	Interventions of interest are: • Wearable cardioverter defibrillator	Comparators of interest are: • Usual clinical care	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity

DESCRIPTION

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

OBJECTIVE

The objective of this evidence review is to assess whether the use of a wearable cardioverter defibrillator improves net health outcome in individuals with a temporary contraindication to implantable cardioverter defibrillator, or as a bridge to implantable cardioverter defibrillator placement, heart transplantation, or recovery.

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.

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.

The initial U.S. Food and Drug Administration (FDA)-labeled indication for WCDs was 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 (ie, 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 (ie, 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; and

- Patients who refuse device therapy.

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.

POLICY

A. Use of wearable cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death is considered **medically necessary** as interim treatment for any of the following:

1. Left ventricular ejection fraction (LVEF) ≤35 percent less than 40 days post myocardial infarction (MI). Reevaluation of LVEF should occur one to three months after the MI. If LVEF remains ≤35 percent on follow-up assessment, despite appropriate medical therapy, ICD implantation is indicated and should be considered; **OR**

2. LVEF ≤35 percent who have undergone coronary revascularization with coronary artery bypass graft (CABG) surgery in the past three months. LVEF should be reassessed three months following CABG. If a sustained ventricular tachyarrhythmia has occurred, or if the LVEF remains ≤35 percent three months after CABG, implantation of an ICD is usually indicated; **OR**

3. Severe but potentially reversible cardiomyopathy, such as tachycardia- or myocarditis-associated cardiomyopathy, while awaiting improvement in LV function, ICD implantation, or if needed, cardiac transplantation; **OR**

4. Severe heart failure awaiting heart transplantation whose anticipated waiting time to transplant is short; **OR**

5. When an ICD is indicated but a delay is required due to a temporary co-morbid condition (ie, infection, recovery from surgery, lack of vascular access).

B. Use of wearable cardioverter defibrillators for the prevention of sudden cardiac death is considered **experimental / investigational** for all other indications.

C. Automatic External Defibrillators for Home Use
The purchase or rental of an automated external defibrillator is an **exclusion** of the member's contract.

POLICY GUIDELINES

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

B. Individuals under the age of 18 must weigh at least 41 pounds and have a chest circumference 26 inches or more, about the average size of an eight year old.

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.

RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through March 18, 2025.

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 individuals 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.

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.

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.[6,] 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 form 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.[7,] 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.[8,] 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.[9,] 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 (eg, defibrillating pads reversed and not directed to the skin) with 1 SCD in a patient with reversed leads.[10,] 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.[11,]

In a 2022 study of the ASSURE WCD device, 130 patients with ICD were fitted with the WCD and followed for 30 days.[12,] 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 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 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.[13,] 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 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.[10,] 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	Follow-up
Feldman et al (2004)[10,]; 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)[11,]; 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 Implantable Cardioverter Defibrillator

Trial	Appropriate Shock[a]	Inappropriate Shock[a]	Nonadherence
Feldman et al (2004)[10]; 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)[11]; 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 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 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-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 Trials
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.[14,15,] 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).[16,] 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 Trials

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.[17,] Four studies (Chung et al [2010];[5,] Epstein et al [2013], described in detail below;[18,] 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.[18,] 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.[19,] 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- Myocardial Infarction Period

Study	Study Type	Country	Dates	Participants	Treatment	Follow-up
Epstein et al (2013)[18,]	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)[19,]	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- Myocardial Infarction Period

Study	Outcomes
Epstein et al (2013)[18,]	N=8453
WCD	• Number of patients receiving shock: n=133 • Shock events: n=146 • Appropriate shocks[a]: 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)[19,]	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 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 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).[20,]

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).[21,] 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),[18,] and 1 conference abstract) were identified; they reported outcomes for WCDs after coronary revascularization for patients with a LVEF of 35% or less.[17,] 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- Coronary Artery Bypass Graft Surgery at High-Risk for Lethal Arrhythmias

Study	Study Type	Country	Dates	Participants	Treatment	Comparator	Follow-up
Zishiri et al (2013)[21,]	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- Coronary Artery Bypass Graft 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)[21,]				
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 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 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.[22,] 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.[23,] 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)[22,]	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)[23,]	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)[22,]			
WCD	7/121 (6%)	2/121 (2%)	Average of 20 hours/day
Wäßnig et al (2016)[23,]			
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.[10,] Rao et al (2011) published a case series of 162 patients with congenital structural heart disease or inherited arrhythmias treated with

WCD.[24,] 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 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 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).[25,] 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.[11,] 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.[26,] 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.[23,] 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[27,] from the full cohort.[28,]

The Uyei and Braithwaite (2014) systematic review also identified 4 studies (Saltzberg et al [2012],[29,] Chung et al [2010],[5,] and 2 conference abstracts) that assessed WCD use in newly

diagnosed nonischemic cardiomyopathy.[17,] 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)[11,]; WEARIT-II Registry	Prospective registry	U.S., Germany	2011-2014	Patients with nonischemic cardiomyopathy	WCD	90 days
Salehi et al (2016)[26,]	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)[27,28,]; PROLONG	Retrospective cohort	Germany	2012-2016	Newly diagnosed LVEF ≤35%	WCD	11 months
Wäßnig et al (2016)[23,]	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)[11,]; WEARIT-II Registry	927		
WCD	Not reported	Not reported	Not reported
Salehi et al (2016)[26,]			
WCD	7/127 (6%)	13/127 (10.2%)	
Duncker et al (2017)[27,28,]; PROLONG			
WCD	8/117 (7%)	None	Of 156 (entire cohort), 48 terminated WCD treatment before 3-month follow-up. Of the 48, 24

Study; Trial	Appropriate Shock[a]	Inappropriate Shock[a]	Nonadherence
			(50%) discontinued due to noncompliance.
Wäßnig et al (2016)[23,]			
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 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 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 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.[29,] 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.

Duncker 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.[30,] 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.[31,] 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 Wearable Cardioverter Defibrillator 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%.[32,] 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.[33,] 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 Wearable Cardioverter Defibrillator 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.

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
Ongoing			
NCT05135403[a]	ASSURE WCD Clinical Evaluation - Post Approval Study (ACE-PAS)	5179	Feb 2025
NCT06570902	Prospective WCD Post CABG Registry	910	May 2030
Unpublished			
	EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry[b]		ongoing

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

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
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
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

REVISIONS	
04-22-2011	Description section updated
	In Policy section: ▪ Clarified wording for C. Automatic External Defibrillators for Home Use From: "The use of automatic external defibrillators by lay persons is considered experimental and investigational because they have not been proven to reduce mortality compared to implantable cardioverter defibrillators or cardiopulmonary resuscitation by first responders. The coverage of automatic external defibrillators used by lay persons is an exclusion of the member's contract." To: "The purchase or rental of an automated external defibrillator is an exclusion of the member's contract." ▪ There is no change in the policy intent.
	In Coding section: ▪ Removed CPT code: 33222
	Rationale section added
	References updated
02-01-2012	In Policy section:

REVISIONS	
	▪ In A 7 removed the word "documented" to read, "Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, prior myocardial infarction (MI), at least 40 days post MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%;" ▪ In B 1 added "b. ischemic dilated cardiomyopathy; or c. non-ischemic dilated cardiomyopathy with NYHA Class II or III heart failure and left ventricular ejection fraction (LVEF) less than or equal to 35%" ▪ In B 2 removed the following indications: "a. Patients with a history of an acute myocardial infarction (MI) within the last 40 days b. Patients with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation c. Patients with a history of psychiatric disorders that interfere with the necessary care and follow-up d. Patients in whom a reversible triggering factor for VT/VF can be definitely identified, such as ventricular tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities e. Patients with terminal illnesses"
	In Coding section: ▪ Revised CPT nomenclature (effective 01/01/12): 33218, 33220, 33224, 33225, 33226, 33240, 33241, 33249 ▪ Added CPT codes (effective 01/01/12): 33230, 33231, 33262, 33263, 33264 ▪ Added Diagnosis codes: 411.0, 412, 414.00-414.07, 425.11, 425.18, 426.82, 745.0-745.9, 746.0-746.9
04-08-2013	Updated Description section
	▪ Updated Implantable Cardioverter-Defibrillators (ICD) policy wording to the current wording from: "A. Implantable Cardioverter-Defibrillators The use of an implantable cardioverter-defibrillator is considered medically necessary for the treatment of ventricular tachyarrhythmias and for the prevention of sudden cardiac death when one of the following indications is present: 1. History of cardiac arrest due to ventricular fibrillation (VF) or ventricular tachycardia (VT) and which is not due to reversible or transient causes; or 2. Spontaneous sustained VT, in patients with structural heart disease; or 3. Spontaneous sustained VT, in patients without structural heart disease, that is not amenable to other treatments; or 4. Syncope of undetermined origin with clinically relevant, hemodynamically significant, sustained VT or VF induced at electrophysiological study when drug therapy is ineffective, not tolerated, or not preferred; or 5. Familial or inherited conditions with a high risk for life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy; or 6. Previous myocardial infarction and coronary artery disease (CAD), at least 40 days post myocardial infarction and three months post coronary artery revascularization surgery with an ejection fraction equal to or less than 35% after maximal medical therapy; or 7. Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II or III heart failure, prior myocardial infarction (MI), at least 40 days post MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%; or

REVISIONS	
	8. Non-ischemic dilated cardiomyopathy (NIDCM) of greater than 9 months duration along with, NYHA Class II or III heart failure, and measured LVEF less than or equal to 35%." ▪ Added indication for Subcutaneous ICD as experimental / investigational to read, "The use of a subcutaneous ICD is considered experimental / investigational for all indications in adult and pediatric patients." ▪ Updated Wearable Cardioverter-Defibrillators policy wording to the current wording from: "B. Wearable Cardioverter Defibrillators (WCD) 1. The wearable cardioverter defibrillator is considered medically necessary for patients at high-risk of sudden cardiac arrest, who meet the following criteria: a. Patients must meet the medical necessity criteria for an implantable cardioverter defibrillator (ICD); or b. ischemic dilated cardiomyopathy; or c. non-ischemic dilated cardiomyopathy with NYHA Class II or III heart failure and left ventricular ejection fraction (LVEF) less than or equal to 35% AND d. Patients must have ONE of the following documented medical contraindications to ICD implantation: 1) Patients awaiting a heart transplantation - on waiting list and meets medical necessity criteria for heart transplantation; or 2) Patients with a previously implanted ICD that requires explanation due to infection with waiting period before ICD reinsertion; or 3) Patients with an infectious process or other temporary condition that precludes initial implantation of an ICD. 2. The wearable cardioverter defibrillator is considered not medically necessary for all other indications."
	Updated Rationale section
	In Coding section: ▪ Added CPT codes: 0319T, 0320T, 0321T, 0322T, 0323T, 0324T, 0325T, 0326T, 0327T, 0328T (effective 01-01-2013) ▪ Removed CPT codes: 33202, 33203, 33226 as these codes were determined to be not applicable to this policy. Updated nomenclature for CPT codes: 33218, 93292, 93745
	Removed Revision details from the 08-3-2010 revision.
	Updated References
01-01-2014	In Coding section: ▪ Revised nomenclature for CPT code: 33223 (Eff 01-01-2014) ▪ Added ICD-10 codes.
01-01-2015	In Coding section: ▪ Added CPT Codes: 33270, 33271, 33272, 33273, 93260, 93261, 93644 (Effective January 1, 2015) ▪ Deleted CPT Codes: 0319T, 0320T, 0321T, 0322T, 0323T, 0324T, 0325T, 0326T, 0327T, 0328T (Effective January 1, 2015)
05-01-2016	Policy title revised from "Cardioverter-Defibrillators." Policy separated into "Wearable Cardioverter Defibrillators" and "Implantable Cardioverter Defibrillators."
	Updated Description section.
	In Policy section: ▪ Added Item A and B. Removed the following: A. Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered medically necessary as interim treatment for any of the following:

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	1. Left ventricular ejection fraction (LVEF) ≤35 percent less than 40 days postmyocardial infarction (MI). Reevaluation of LVEF should occur one to three months after the MI. If LVEF remains ≤35 percent on follow-up assessment, despite appropriate medical therapy, ICD implantation is indicated and should be considered; or 2. LVEF ≤35 percent who have undergone coronary revascularization with coronary artery bypass graft (CABG) surgery in the past three months. LVEF should be reassessed three months following CABG. If a sustained ventricular tachyarrhythmia has occurred, or if the LVEF remains ≤35 percent three months after CABG, implantation of an ICD is usually indicated; or 3. Severe but potentially reversible cardiomyopathy, such as tachycardia- or myocarditis-associated cardiomyopathy, while awaiting improvement in LV function, ICD implantation, or if needed, cardiac transplantation; or 4. Severe heart failure awaiting heart transplantation whose anticipated waiting time to transplant is short; or 5. When an ICD is indicated but a delay is required due to a temporary co-morbid condition (ie infection, recovery from surgery, lack of vascular access); or 6. Temporary treatment of potentially treatable or reversible life threatening ventricular arrhythmias ▪ Previous Item III B is now Item C in this policy. ▪ Previous Item IV is now Item D in this policy.
	Updated Rationale section.
	Updated References section.
08-04-2016	Updated Description section.
	In Policy section: ▪ Removed "1. Meet the criteria for an implantable cardioverter defibrillator (the indications below are included in the *Implantable Cardioverter Defibrillators* medical policy) • Primary Prevention a) 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 b) 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 c) 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 d) 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 nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.

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	e) Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines): i. Congenital long QT syndrome; OR ii. Brugada syndrome; OR iii. Short QT syndrome; OR iv. Catecholaminergic polymorphic ventricular tachycardia • Secondary Prevention a) Patients with a history of life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (eg, acute ischemia) have been excluded. AND 1. have a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time; AND 2. have been scheduled for an ICD placement or who had an ICD removed and have been rescheduled for placement of another ICD once the contraindication is treated. B. Use of WCDs for the prevention of sudden cardiac death is considered experimental / investigational for the following indications when they are the sole indication for a wearable cardioverter defibrillator: 1. Patients in the immediate (ie, <40 days) period following an acute myocardial infarction. 2. Patients post-CABG surgery 3. Patients with newly diagnosed nonischemic cardiomyopathy 4. Women with peripartum cardiomyopathy 5. High-risk patients awaiting heart transplant" ▪ Added "1. Left ventricular ejection fraction (LVEF) ≤35 percent less than 40 days postmyocardial infarction (MI). Reevaluation of LVEF should occur one to three months after the MI. If LVEF remains ≤35 percent on follow-up assessment, despite appropriate medical therapy, ICD implantation is indicated and should be considered; or 2. LVEF ≤35 percent who have undergone coronary revascularization with coronary artery bypass graft (CABG) surgery in the past three months. LVEF should be reassessed three months following CABG. If a sustained ventricular tachyarrhythmia has occurred, or if the LVEF remains ≤35 percent three months after CABG, implantation of an ICD is usually indicated; or 3. Severe but potentially reversible cardiomyopathy, such as tachycardia- or myocarditis-associated cardiomyopathy, while awaiting improvement in LV function, ICD implantation, or if needed, cardiac transplantation; or 4. Severe heart failure awaiting heart transplantation whose anticipated waiting time to transplant is short; or 5. When an ICD is indicated but a delay is required due to a temporary co-morbid condition (ie, infection, recovery from surgery, lack of vascular access)."
	Updated Rationale section.
	Updated References section.
07-11-2017	Updated Description section.
	Updated Rationale section.

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	Updated References section.
10-01-2017	In Coding section: ▪ Added ICD-10 codes: I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89.
06-22-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.
	Updated References section.
06-19-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-23-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.
07-02-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.
07-01-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed Coding Bullets o The following CPT code describes interrogation of a wearable cardioverter defibrillator device: 93292. This code cannot be reported with code 93745. o The following CPT code describes the professional services involved in the initial setup and programming of this device: 93745. o The following HCPCS codes are specific to this device: K0606, K0607, K0608, K0609. ▪ Converted ICD-10 codes to ranges
	Updated References Section
06-27-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section
06-27-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
06-24-2025	Updated Description Section
	Updated Rationale Section
	Updated Reference Section

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