Wearable Cardioverter-Defibrillators

**Policy Number:** 2.02.15  
**Last Review:** 12/2019  
**Origination:** 10/1988  
**Next Review:** 12/2020

**Policy**
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for a wearable cardioverter-defibrillator when it is determined to be medically necessary because the criteria shown below are met.

**When Policy Topic is covered**
Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **medically necessary** as interim treatment for those who:
- meet the criteria for an implantable cardioverter-defibrillator (see indications in separate policy); and
- have a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time; and
- 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.

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **medically necessary** in the following situations.
- Either documented prior myocardial infarction or dilated cardiomyopathy and a measured LVEF less than or equal to 35%; or
- Familial or inherited conditions with a high risk of life-threatening VT such as long QT syndrome or hypertrophic cardiomyopathy.

Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **medically necessary** as a bridge to ICD placement for patients within 40 days post myocardial infarction (MI) who have ventricular tachycardia/ventricular fibrillation (VT/VF) occurring > 48 hours after index MI.

**When Policy Topic is not covered**
Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered **investigational** for the following indications when they are the sole indication for a wearable cardioverter-defibrillator:
- Patients in the immediate (i.e., less than 40 days) period following an acute myocardial infarction, except as noted above.
- Patients post-CABG [coronary artery bypass graft] surgery
- Women with peripartum cardiomyopathy
- High-risk patients awaiting heart transplant

Use of wearable cardioverter-defibrillators is considered **investigational** for all other indications.

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

### Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| 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  
- 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 |
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.

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

**Immediate Post Myocardial Infarction**
For individuals who are in the immediate post myocardial infarction period who receive a WCD, the evidence includes randomized controlled trials (RCTs) and a technology assessment that assess ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs have reported that OS did not improve after treatment with a permanent ICD. While both trials reported a decrease in sudden cardiac death, there was a corresponding increase in non-sudden cardiac death events, resulting in no net survival benefit. Analysis of data from a retrospective postmarket registry with WCD reported a success rate of 82% but interpretation of registry data is limited in absence of a control group. Given the lack of evidence that a permanent ICD improves outcomes in the immediate post myocardial infarction period, a WCD would not be expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Other High-Risk Conditions**
For individuals who are post coronary artery bypass graft surgery and are at high-risk for lethal arrhythmias, awaiting heart transplantation and at high-risk for lethal arrhythmias, have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes an RCT evaluating early ICD placement after coronary artery bypass graft, and case series and registry data for other indications that assess ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, an RCT reported no difference in OSs associated with early ICD placement. For other indications, there are no RCTs that demonstrate benefit of an ICD placement. Because of absence of any benefit of ICD and lack of any RCTs to demonstrate benefit of a WCD, the evidence does not currently permit
conclusions that a WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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 and reduced ejection fraction.

ICDs consist of implantable leads, which are placed percutaneously in the heart, that are connected to a pulse generator placed beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See separate policy 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 sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. The potential indications include:

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

**Regulatory Status**
In 2001, the Lifecor WCD® 2000 system was approved by 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 Zoll LifeVest®.

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

**Rationale**
This evidence review was created in April 2003 and has been updated with regularly with searches of the MEDLINE database. The most recent literature update was performed through March 4, 2019.

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

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

**Wearable Cardioverter Defibrillator**
Clinical Context and Therapy Purpose
The purpose of WCD in patients who have risk of sudden death from cardiac arrest is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

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

Patients
The relevant population(s) of interest are patients at risk of death from cardiovascular arrest. Specific indications that will be reviewed include patients who have a contraindication to an implantable cardioverter defibrillator or who are:

- In the immediate post myocardial infarction period
- Post coronary artery bypass graft surgery and are at high-risk for lethal arrhythmias
- Awaiting heart transplantation and are at high-risk for lethal arrhythmias
- With newly diagnosed nonischemic cardiomyopathy
- 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 survival over ten year follow-up, heart attacks, function, and appropriate and inappropriate shocks from the WCD

Overview of wearable cardioverter defibrillator vs implantable cardioverter defibrillator
The available evidence on the WCD consists of case series describing outcomes from patients using the device. There are no RCTs comparing WCD with standard care or alternative treatments. RCTs of patients undergoing permanent ICD placement can provide indirect evidence on the efficacy of the WCD if the (1) indications for a permanent ICD are similar to the indications for WCD and (2) performance of the WCD has been shown to approximate that of a permanent ICD. It was on this basis that a TEC Assessment (2010) found that the evidence was sufficient to conclude that the WCD can successfully terminate malignant ventricular arrhythmias. Assessment conclusions were based on several factors. First, there is a strong physiologic rationale for the device. It is known that sensor leads placed on the skin can successfully detect and characterize arrhythmias. It is also established that a successful countershock can be delivered externally. The use of external defibrillators is extensive, ranging from in-hospital use to public
access placement and home use. Its novelty is in the way that the device is packaged and utilized. Second, some evidence has suggested the device successfully terminates arrhythmias.

Two uncontrolled studies were identified that directly tested the efficacy of the WCD. The first was a small case series (15 patients) by Auricchio et al (1998) who reported on survivors of sudden cardiac arrest scheduled to receive an ICD. 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 nine of ten cases and successfully terminated the arrhythmia in all nine 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. 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. 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. The WCD was never used by 8 patients, and 27% patients wore the device more than 90% of the day. Patients who were followed for 72 days wore the WCD for a mean of 14.1 hours per day. Additionally, during follow-up, no arrhythmias or shock were detected. Kao et al (2012) reported on the results of a prospective registry of 82 heart failure patients eligible for WCDs. Of these, 16% (n=13) did not wear the WCD due to refusal, discomfort, or other/unknown reasons. In the Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death (WEARIT) and Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months (BIROAD) studies (later combined), the two unsuccessful defibrillations occurred in patients with incorrectly placed therapy electrodes (e.g., defibrillating pads reversed and not directed to the skin) with one SCD in a patient with reversed leads. These results suggested that the WCD might be inferior to an ICD, due to suboptimal adherence and difficulty with correct placement of the device. Therefore, these data corroborate the assumption that the WCD should not be used as a replacement for an ICD but only considered in those situations in which the patient does not meet criteria for a permanent ICD. However, high compliance with the WCD with a median daily use of 22.5 hours was reported in the Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients...
(WEARIT-II) Registry, a large prospective study with 2000 patients from a real-world setting.10.

**Section Summary: WCD vs ICD**
No studies have directly compared the performance of a WCD with a permanent ICD. One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice might be inferior to a permanent ICD.

**Temporary Contraindications to an ICD**
Contraindications to an ICD are few. According to the American College of Cardiology and American Heart Association (1998) guidelines on ICD use, the device is contraindicated in patients with terminal illness, in patients with drug-refractory class IV heart failure, in patients who are not candidates for transplantation, and in patients with a history of psychiatric disorders that interferes with the necessary care and follow-up postimplantation.11 It is not known how many patients refuse an ICD placement after it has been recommended. A subset of patients who may otherwise meet the established criteria for an ICD (see evidence review 7.01.44) but may have a temporary contraindication for an implantable device such as infection may benefit from WCD. Similarly, a patient with an existing ICD and concurrent infection may benefit this group during the time before reinsertion of ICD may be attempted.

Study characteristics and results of two 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

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

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

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

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Appropriate Shock(^a)</th>
<th>Inappropriate Shock(^a)</th>
<th>Nonadherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feldman et al (2004)(^9); WEARIT and BIROAD</td>
<td>289</td>
<td>289</td>
<td>289</td>
</tr>
<tr>
<td>WCD, n/N (%)</td>
<td>6/8 (75%)</td>
<td>0.67 per month of use</td>
<td>6 sudden deaths: 5 not wearing; 1 incorrectly wearing the device</td>
</tr>
<tr>
<td>WCD, n/N (%)</td>
<td>22/41 (54%)</td>
<td>10 (0.5%) patients</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

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

**Section Summary: Temporary Contraindications to an ICD**
A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. Prospective cohort studies have established that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. These patients are expected to benefit from an ICD, and use of a WCD is a reasonable alternative because there are no other options for automatic detection and termination of ventricular arrhythmias.

**Immediate Post myocardial infarction Period**
Evidence on the use of a WCD in the immediate postMI period as a bridge to permanent ICD placement was reviewed in a TEC Assessment (2010). 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], 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 left ventricular ejection fraction (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. The hazard ratio (HR) for overall survival (OS) in the DINAMIT and IRIS trial were 1.08 (95% confidence interval [CI], 0.76 to 1.55; p=0.66) and 1.04 (95% CI, 0.81 to 1.35; p=0.78), 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 two 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=0.92). 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=0.001).

Epstein et al (2013) reported on the results of a postmarket registry data from 8453 post-MI patients who received WCDs for risk of sudden cardiac arrest while awaiting ICD placement. 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.

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

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

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>FU</th>
</tr>
</thead>
</table>

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

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epstein et al (2013)</td>
<td>N=8453</td>
</tr>
<tr>
<td>Wearable cardioverter</td>
<td>• Number of patients receiving shock: 133</td>
</tr>
</tbody>
</table>
defibrillator

- Shock events: 146
- Appropriate shocks: 309
- Shocks successful in terminating VT or VF: 252 (82% success)
- Shocks leading to asystole: 9
- Unsuccessful shocks: 41 (10% failure)
- Inappropriate shocks: 99 patients received 114 inappropriate shocks

VF: ventricular fibrillation; VT: ventricular tachycardia.

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

Section Summary: Immediate Post MI Period

Two RCTs of ICD use in the early postacute MI 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 absence of a control group. 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

Evidence on use of early ICD placement in high-risk postCABG patients with a low LVEF and abnormalities on signal-averaged electrocardiography consists of an RCT (CABG Patch) that reported no difference in overall mortality between the ICD and the control groups (HR=1.07; 95% CI, 0.81 to 1.42). Zishiri et al (2013) reported on the results of a nonrandomized comparison of nearly 5000 patients with LVEF of 35% or less from 2 separate cohorts who underwent revascularization with CABG or percutaneous coronary intervention (809 patients discharged with a WCD from a national registry and 4149 patients discharged without WCD from Cleveland Clinic CABG and percutaneous coronary intervention registries). Study characteristics and results are summarized in Tables 5 and 6, respectively. 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), Epstein et al (2014), 1 conference abstract) were identified; they reported outcomes for WCDs after coronary revascularization for patients with a LVEF of 35% or less. 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zishiri et al</td>
<td>Retrospective matched cohort</td>
<td>U.S.</td>
<td>2002-2009</td>
<td>Patients with low-EF post-PCI or post-CABG</td>
<td>WCD</td>
<td>No WCD</td>
<td>3.2</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Post-CABG Mortality (90 Days)</th>
<th>Post-PCI Mortality (90 Days)</th>
<th>Post-CABG Mortality (Long-Term)</th>
<th>Post-PCI Mortality (Long-Term)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zishiri et al</td>
<td>7/26 (3.1%)</td>
<td>5/288 (1.7%)</td>
<td>19/226 (8.4%)</td>
<td>31/228 (11%)</td>
</tr>
<tr>
<td>WCD, n/N (%)</td>
<td>7/26 (3.1%)</td>
<td>5/288 (1.7%)</td>
<td>19/226 (8.4%)</td>
<td>31/228 (11%)</td>
</tr>
<tr>
<td>No WCD, n/N (%)</td>
<td>135/2198 (6.1%)</td>
<td>189/1951 (9.7%)</td>
<td>636/2198 (29%)</td>
<td>763/1951 (39%)</td>
</tr>
</tbody>
</table>

HR (95% CI); p 0.619 (0.385 to 0.997); adjusted p=0.048a 0.430 (0.290 to 0.638); <0.001a

CABG: coronary artery bypass graft; CI: confidence interval; HR: hazard ratio; PCI: percutaneous coronary intervention; WCD: wearable cardioverter defibrillator.

a Multivariable Cox proportional hazards analyses.

Section Summary: Patients Post CABG Surgery at High-Risk for Lethal Arrhythmias

For high-risk post-CABG patients, the evidence includes 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**

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. 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 two patients who died while wearing the WCD had asystole.

Wässnig et al (2016) reported on the results of a national German registry of 6043 patients with multiple etiologies including dilated cardiomyopathy, myocarditis, and ischemic and nonischemic cardiomyopathies who were prescribed WCD. Study characteristics and results are summarized in Tables 7 and 8, respectively. Overall, 1 (2.5%) of 40 patients awaiting heart transplantation was appropriately shocked for sustained VT or VF.

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wässnig et al (2016)</td>
<td>Retrospective cohort</td>
<td>Germany, multiple sites</td>
<td>2010-2013</td>
<td>Patients with multiple etiology</td>
<td>WCD</td>
<td>NR</td>
</tr>
</tbody>
</table>

FU: follow-up; HT: heart transplant; NR: not reported; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.
Table 8. Key Nonrandomized Trial Results in Patients Awaiting Heart Transplantation at High-Risk for Lethal Arrhythmias

<table>
<thead>
<tr>
<th>Study</th>
<th>Appropriate Shock&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Inappropriate Shock&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opreanu et al (2015)&lt;sup&gt;16&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WCD</td>
<td>7/121 (6%)</td>
<td>2/121 (2%)</td>
<td>Average of 20 h/d</td>
</tr>
<tr>
<td>Wässning et al (2016)&lt;sup&gt;19&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WCD</td>
<td>1/40 (2.5%)</td>
<td>Stratified data not reported</td>
<td>Stratified data not reported</td>
</tr>
</tbody>
</table>

WCD: wearable cardioverter defibrillator.
<sup>a</sup>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.<sup>9</sup> Rao et al (2011) published a case series of 162 patients with congenital structural heart disease or inherited arrhythmias treated with WCD.<sup>20</sup> 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 one month, but none was related to cardiac causes. Two patients received three appropriate shocks for VT or VF, and four patients received seven 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 manufacturer registry, a subset from a prospective cohort, and a case series. These studies do not provide sufficient evidence to determine whether a WCD improves outcomes compared with usual care.
**Newly Diagnosed Nonischemic Cardiomyopathy**

In patients with newly diagnosed nonischemic cardiomyopathy, final EF is uncertain because some patients show an improvement in EF over time. The 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=0.08). A post hoc analysis of the same trial by Kadish et al (2006) evaluated use of an ICD in patients with nonischemic dilated cardiomyopathy and examined the benefit of ICD use by time since diagnosis (<3 months and >9 months).\(^{21}\) This trial excluded patients with a clinical picture consistent with a reversible cause of cardiomyopathy and thus may differ from the population considered for a WCD. The difference in survival was of borderline significance for the ICD group compared with controls, both for the recently diagnosed subgroup (HR=0.38; 95% CI, 0.14 to 1.00; p=0.05) and the remotely diagnosed subgroup (HR=0.43; 95% CI, 0.22 to 0.99; p=0.046).

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

Another potential indication for the WCD is alcoholic cardiomyopathy where cardiomyopathy is reversible but temporary protection against arrhythmias is needed. Salehi et al (2016) reported on the results of analysis of a subset of patients identified from manufacturer registry.\(^{22}\) Mean EF was 19.9% on presentation. Patients wore the WCD for a median of 51 days and a median of 18.0 hours a day. At the end of WCD use, 33% of patients had improved EF and did not require ICD placement; 24% received an ICD. Four deaths occurred during this period, with one 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.\(^{19}\) 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\(^{23}\) from the full cohort.\(^{24}\).
The Uyei and Braithwaite (2014) systematic review also identified 4 studies (Saltzberg et al [2012], Chung et al [2010], 2 conference abstracts) that assessed WCD use in newly diagnosed nonischemic cardiomyopathy. In the 3 studies that reported VT and VF incidences, on average, 0.57% (5/871) subjects experienced VT and/or VF over a mean duration of 52.6 days. Among those who experienced a VT or VF event, on average, 80% had successful event termination.

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

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kutyifa et al (2015); WEARIT-II Registry</td>
<td>Prospective registry</td>
<td>U.S., Germany</td>
<td>2011-2014</td>
<td>Patients with nonischemic cardiomyopathy</td>
<td>WCD</td>
<td>90 d</td>
</tr>
<tr>
<td>Duncker et al (2017); PROLONG</td>
<td>Retrospective cohort</td>
<td>Germany</td>
<td>2012-2016</td>
<td>Newly diagnosed LVEF ≤35%</td>
<td>WCD</td>
<td>11 mo</td>
</tr>
<tr>
<td>Wässnig et al (2016)</td>
<td>Retrospective cohort</td>
<td>Germany, multiple sites</td>
<td>2010-2013</td>
<td>Patients with multiple etiology</td>
<td>WCD</td>
<td>NR</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Appropriate Shocka</th>
<th>Inappropriate Shocka</th>
<th>Nonadherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kutyifa et al (2015); WEARIT-II</td>
<td>927</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>-----</td>
<td>---------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td>WCD</td>
<td>Not reported</td>
<td>7/127 (6%)</td>
<td>13/127 (10.2%)</td>
</tr>
<tr>
<td>WCD</td>
<td>8/117 (7%)</td>
<td>None</td>
<td>Of 156 (entire cohort), 48 terminated WCD treatment before 3-mo follow-up. Of the 48, 24 (50%) discontinued due to noncompliance.</td>
</tr>
<tr>
<td>WCD</td>
<td>7/735 (1%)</td>
<td>Stratified data not reported</td>
<td>Stratified data not reported</td>
</tr>
</tbody>
</table>

WCD: wearable cardioverter defibrillator.

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

**Section Summary: Newly Diagnosed Nonischemic Cardiomyopathy**

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

**Peripartum Cardiomyopathy**

Saltzberg et al (2012) retrospectively analyzed a subset of 107 women with peripartum cardiomyopathy treated with a WCD device and compared with a matched sample of 159 nonpregnant women who had nonischemic dilated cardiomyopathy. The event rate was 0 in the peripartum cardiomyopathy over an average 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. 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 three patients, four 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 five patients without WCD, no episodes of syncope or ventricular arrhythmia or deaths occurred.

Section Summary: Peripartum Cardiomyopathy
For peripartum cardiomyopathy, evidence includes a retrospective analysis of registry data 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.

Summary of Evidence

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

Immediate Post MI
For individuals who are in the immediate post MI period who receive a WCD, the evidence includes RCTs and a technology assessment that assess ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs have reported that OS did not improve after treatment with a permanent ICD. While both trials reported a decrease in SCD, there was a corresponding increase in non-SCD events, resulting in no net survival benefit. Analysis of data from a retrospective postmarket registry with WCD reported a success rate of 82% but interpretation of registry data is limited in absence of a control group. Given the lack of evidence that a permanent ICD improves outcomes in the immediate post myocardial infarction period, a WCD would not be expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.
Other High-Risk Conditions
For individuals who are post CABG surgery and are at high-risk for lethal arrhythmias, awaiting heart transplantation and at high-risk for lethal arrhythmias, have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes an RCT evaluating early ICD placement after CABG, and case series and registry data for other indications that assess ICD devices, given the absence of evidence on WCD devices. The relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post CABG patients, an RCT reported no difference in OS associated with early ICD placement. For other indications, there are no RCTs that demonstrate benefit of an ICD placement. Because of absence of any benefit of ICD and lack of any RCTs to demonstrate benefit of a WCD, the evidence does not currently permit conclusions that a WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

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 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 ad while this policy was under review in 2013. Overall, the input was mixed. Most, but not all, providing comments suggested that the WCD may have a role in select high-risk patients following acute myocardial infarction or in newly diagnosed cardiomyopathy. However, reviewers acknowledged the lack of evidence for benefit and consistency in the evidence in defining high-risk subgroups that may benefit.

2010 Input
In response to requests, input was received from 4 academic medical centers while this policy was under review in 2010. Most, but not all, providing comment
suggested that the WCD may have a role in select high-risk patients following acute myocardial infarction or in newly diagnosed cardiomyopathy.

2008 Input
In response to requests, input from physician specialty societies and academic medical centers was not received while this policy was under review in 2008.

Practice Guidelines and Position Statements

American Heart Association et al
The AHA, the American College of Cardiology and the Heart Rhythm Society (2018) published a guideline on the management of patients with ventricular arrhythmias and prevention of sudden cardiac death.27 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 NICM, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT/SCA. 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. Class IIa is moderate recommendation, and class IIb is a weak recommendation.

Table 11. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection, the wearable cardioverter-defibrillator is reasonable for the prevention of SCD).&quot;</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
<tr>
<td>&quot;In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed, NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable.&quot;</td>
<td>IIb</td>
<td>B-NR</td>
</tr>
</tbody>
</table>

B-NR: Level B - nonrandomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NICM: non-ischemic cardiomyopathy; SCA: sudden cardiac arrest; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

The AHA (2016) published a scientific advisory on the WCD.28 The AHA stated that "because there is a paucity of prospective data supporting the use of the WCD, particularly in the absence of any published, randomized, clinical trials, the recommendations provided in this advisory are not intended to be prescriptive or to suggest an evidence-based approach to the management of patients with FDA-approved indications for use." The specific recommendations are summarized in Table 12.
**Table 12. Guidelines for WCD Therapy**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;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.&quot;</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>&quot;Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation&quot;</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>&quot;WCDs may be appropriate as bridging therapy in situation associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 D of MI.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>&quot;WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive &gt;6 mo.&quot;</td>
<td>III</td>
<td>C</td>
</tr>
</tbody>
</table>

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; MI: myocardial infarction; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

**American College of Cardiology et al**

The American College of Cardiology, AHA, and the Heart Rhythm Society jointly published guidelines on the management of adults who have ventricular arrhythmias or who are at risk for sudden cardiac death, including diseases and syndromes associated with a risk of sudden cardiac death from ventricular arrhythmias. Recommendations related to the use of WCDs are provided in Table 13.

**Table 13. Guidelines for WCD Therapy**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>In patients with an implantable cardioverter defibrillator and a history of sudden cardiac arrest or sustained ventricular arrhythmia in whom removal of the implantable cardioverter defibrillator is required (as with infection), the wearable cardioverter defibrillator is reasonable for the prevention of sudden cardiac death.</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
</tbody>
</table>
In patients at an increased risk of sudden cardiac death but who are not ineligible for an implantable cardioverter defibrillator, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed nonischemic cardiomyopathy, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, wearable cardioverter defibrillator may be reasonable.\(^a\)

\[\text{B-NR: data derived from } \geq 1 \text{ nonrandomized trials or meta-analysis of such studies; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; WCD: wearable cardioverter defibrillator.}\]

\(^a\) Removal of an ICD for a period of time, most commonly due to infection, exposes the patient to risk of untreated ventricular tachycardia/sudden cardiac death unless monitoring and access to emergency external defibrillation is maintained. In 1 series of 354 patients who received the WCD, the indication was infection in 10%.\(^{30}\) For patients with a history of sudden cardiac arrest or sustained ventricular arrhythmia, the WCD may allow the patient to be discharged from the hospital with protection from ventricular tachycardia/sudden cardiac death until the clinical situation allows reimplantation of an ICD.

\(^b\) The patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the WCD. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of ventricular tachycardia or sudden cardiac death. However, the WCD is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time. In patients awaiting transplant, even with anticipated survival <1 year without transplant, and depending on clinical factors such as use of intravenous inotropes and ambient ventricular arrhythmia, a WCD may be an alternative to an ICD.

**International Society for Heart and Lung Transplantation**

The International Society for Heart and Lung Transplantation (2006) issued guidelines on the care of cardiac transplant candidates that addressed use of ICDs or WCDs.\(^{31}\) Recommendations on the use of WCDs are provided in Table 14.

**Table 14. Guidelines on Management of Cardiac Transplant Candidates With ICDs**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;An implanted or wearable ICD should be provided for Status 1B patients [ie, dependent on intravenous medications or a mechanical assist device] who are discharged home given that the wait for transplantation remains significant.&quot;</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>&quot;It is reasonable to consider placement of a defibrillator in patients with Stage D failure who are candidates for transplantation or LVAD destination therapy (see subsequent considerations for MCSD referral: bridge or destination).&quot;</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</table>

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVAD: left ventricular assist device; MCSD: mechanical circulatory support device.

**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 unpublished trials that might influence this review are listed in Table 15.

**Table 15. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01446965&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Prevention of Sudden Death After Myocardial Infarction Using a LifeVest Wearable Cardioverter-defibrillator</td>
<td>1900</td>
<td>July 2019</td>
</tr>
<tr>
<td></td>
<td>EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**REFERENCES**


**Billing Coding/Physician Documentation Information**

**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

**93292** Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system

**93745** Initial set-up and programming by a physician 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

**ICD-10 Codes**

**I42.0-** Cardiomyopathy code range

**I43**

**I47.0-** Paroxysmal tachycardia code range

**I47.9**

**I49.01-** Ventricular fibrillation and flutter code range

**I49.02**

**I50.1-** Heart failure code range

**I50.9**

**Z86.74** Personal history of sudden cardiac arrest
**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

10/1/88  New policy added to the DME section and considered investigational.
8/1/00  Policy Archived.
9/1/05  Policy removed from Archives, remains investigational.
9/1/06  No policy statement changes.
6/1/07  Interim change. Policy updated with literature review through December 2006. Policy statement revised with medically necessary indications for interim treatment.
9/1/07  No policy statement changes.
9/1/08  No policy statement changes.
9/1/09  No policy statement changes.
9/1/10  No policy statement changes.
9/1/11  No policy statement changes.
9/1/12  No policy statement changes.
12/1/13  Added post-CABG surgery, newly diagnosed nonischemic cardiomyopathy and peripartum cardiomyopathy to investigational policy statement. Removed “as a Bridge to Implantable Cardioverter-Defibrillator Placement” from the title.
12/1/14  “High-risk patients awaiting heart transplant” was added to the investigational policy statement; and an additional policy statement that use of wearable cardioverter defibrillators is considered investigational for all other indications was added.
12/1/15  No policy statement changes.
12/1/16  No policy statement changes.
7/1/17  Added additional medically necessary indication.
12/1/17  No policy statement changes.
12/4/17  Added medically necessary indication and removed one of the indications from the first investigational statement.
12/1/18  No policy statement changes.
12/1/19  No policy statement changes.

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