Wearable Cardioverter-Defibrillators

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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.

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.
- Patients post-CABG [coronary artery bypass graft] surgery
- Patients with newly diagnosed non-ischemic cardiomyopathy
- 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>
<tbody>
<tr>
<td>Individuals: • With a temporary contraindication to an implantable cardioverter defibrillator</td>
<td>Interventions of interest are: • Wearable cardioverter defibrillator</td>
<td>Comparators of interest are: • Usual care</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • Who are in the immediate post myocardial infarction period</td>
<td>Interventions of interest are: • Wearable cardioverter defibrillator</td>
<td>Comparators of interest are: • Usual care</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • Who are post coronary artery bypass graft surgery and at high risk for lethal arrhythmias</td>
<td>Interventions of interest are: • Wearable cardioverter defibrillator</td>
<td>Comparators of interest are: • Usual care</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • Who are awaiting heart transplantation and at high risk for lethal arrhythmias</td>
<td>Interventions of interest are: • Wearable cardioverter defibrillator</td>
<td>Comparators of interest are: Usual care</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With newly diagnosed nonischemic cardiomyopathy</td>
<td>Interventions of interest are: • Wearable cardioverter defibrillator</td>
<td>Comparators of interest are: • Usual care</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With peripartum cardiomyopathy</td>
<td>Interventions of interest are: • Wearable cardioverter defibrillator</td>
<td>Comparators of interest are: • Usual care</td>
<td>Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

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 a period of time during which the need for a permanent implantable device is uncertain.
For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The available data establish that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. 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. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence has shown that these patients benefit from a cardioverter defibrillator in general, and the WCD can detect and treat lethal arrhythmias in these patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For the immediate post myocardial infarction period, the evidence does not support the conclusion that the WCD improves outcomes. Two RCTs have reported that overall survival did not improve after treatment with a permanent ICD. While these 2 trials both reported a decrease in sudden cardiac death (SCD), there was a corresponding increase in non-SCD, resulting in no net survival benefit. Similarly, for high-risk post coronary artery bypass graft patients, 1 RCT reported no difference in overall survival associated with early ICD placement. Thus, given the lack of evidence that a permanent ICD improves outcomes for these indications, a WCD is not expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are post coronary artery bypass graft surgery and at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, or have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes case series and registry data. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment–related morbidity. It is not possible to conclude from the available evidence that the WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease. The implantable cardioverter-defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, the use of ICDs has been potentially broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction.
ICDs consist of implantable leads in the heart that connect to a pulse generator implanted beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure, with the ICD device placed under the skin on the chest wall and the cardiac leads placed percutaneously. Potential adverse effects 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 that is intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of a vest that is worn continuously underneath the patient's clothing. Part of this vest is the ‘electrode belt’ that contains the cardiac-monitoring electrodes and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module that is worn on the patient’s belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages.

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001 for “adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator.” The vest was renamed and is now called the Zoll® LifeVest®.

In 2015, 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 periodic literature searches of the MEDLINE database. The most recent literature update was conducted through March 22, 2016.

The available evidence on the wearable cardioverter defibrillator (WCD) consists of case series describing outcomes from patients using the device. There are no randomized controlled trials (RCTs) comparing WCD to standard care or alternative treatments. RCTs of patients undergoing permanent implantable cardioverter defibrillator (ICD) implantation can provide indirect evidence on the efficacy of the WCD if the indications for a permanent ICD are similar to the potential indications for WCD and if the performance of the WCD has been shown to approximate that of a permanent ICD.

U.S. Food and Drug Administration (FDA)–labeled indications for the WCD are adult patients who are 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 population)
- Bridge to implantable device or clinical improvement (ie, the BIROAD population)
  - Post bypass with ejection fraction (EF) less than 30%
  - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
  - Post myocardial infarction with EF 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.

**WCD Effectiveness Compared With ICD Effectiveness**

Very few peer-reviewed studies have reported on clinical outcomes of WCDs and none has evaluated the efficacy of WCD in reducing mortality compared with alternatives. Despite the small amount of evidence, a 2010 TEC Assessment found concluded that the evidence is sufficient to conclude the WCD can successfully terminate malignant ventricular arrhythmias.

Assessment conclusions were based on several factors. First, there is 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 placement and use at home. Its novelty is in the way that the device is packaged and utilized.

Second, there is some evidence that 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) of survivors of SCA scheduled to receive an ICD.

During the procedure to implant 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. In 2010, Chung et al published an evaluation of WCD effectiveness in preventing sudden death 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/VF.

In 2014, Tanawuttiwat et al reported 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 sudden death outside the hospital while not wearing their WCD device.

The WEARIT/BIROAD study evaluated a prospective cohort of 289 patients at high risk for sudden cardiac death (SCD) but who did not meet criteria for an ICD or who could not receive an ICD for several months. Patients were followed for a mean of 3.1 months. During this time, there were 8 documented episodes of arrhythmia requiring shock in 6 separate patients. Six of the 8 episodes were successfully resuscitated by the WCD. By group sequential analysis, the estimate of percent successful resuscitations was 69%. There was 99% confidence that the true rate of success was greater than 25% and 90% confidence that the true rate was greater than 44%. In the 2 cases of unsuccessful defibrillation, the authors reported that the WCD was placed incorrectly, with the therapy electrodes reversed and not directed to the skin.

The WEARIT/BIROAD results underscore the difficulty in proper device use and compliance. Six patients suffered SCA likely due to wearing the device improperly or not wearing the device at all. This implied that a relatively high rate of nonadherence may be the main factor limiting the effectiveness of the WCD. Also, there was a fairly high rate of dropout (22%) over the 3-month follow-up. In a study of 134 consecutive, uninsured patients with cardiomyopathy and a mean EF of 22.5%, Mitrani et al reported noncompliance with a WCD was even greater. The dropout rate was 35%. The WCD was never used by 8 patients, and only 27% 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. In a prospective registry of 82 heart failure patients eligible for WCDs, Kao et al reported 13 patients did not wear the WCD due to refusal, discomfort, or other/unknown reasons. These results suggest that the WCD is likely to 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.

Another potential indication is for patients who are being evaluated for ICD placement. Clinical outcomes for patients prescribed a WCD for a transient or undefined arrhythmia risk who were prospectively enrolled in the WEARIT-II registry were published in abstract form in 2013, with 3-month results published in 2015. WEARIT-II enrolled 2000 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. The median wear time was 90 days, with a median daily use of 22.5 hours. The high compliance rate in this study may have been related to greater compliance in patients who volunteered to participate in the registry. During the WCD trial period there were 120 sustained ventricular tachyarrhythmias in 41 patients. Ninety of the events were withheld from shock therapy by the patients and 30 required shock therapy. Appropriate shock was received by 22 (54%) of the 41 patients, while 10 (0.5%) patients received inappropriate shock. Three patients died while wearing the WCD, all from asystole.
No patients died from VT or VF while wearing the WCD. 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 improved. Follow-up of clinical outcomes is continuing through 12 months.

**Section Summary: WCD Effectiveness Compared With an ICD Effectiveness**
No studies have directly compared the performance of a WCD to 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 percent of successful resuscitations was approximately 70%. In that study, there was a high rate of nonadherence and dropouts, and failures to successfully resuscitate were largely attributed to incorrect use of the device and/or nonadherence. A more recent registry study reported high compliance rate when used as a trial for ICD implantation, though these results may be biased by self-selection. This evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice is likely to be inferior to a permanent ICD.

**WCD as Bridge to ICD, Heart Transplantation, or Recovery**
The WCD can be used in a variety of situations as a bridge to ICD, heart transplantation, or recovery. The specific indications addressed in this review are:
- Temporary contraindications to ICD
- Immediate post myocardial infarction (MI) period
- Patients post coronary artery bypass graft (CABG) surgery who are at high risk for lethal arrhythmias
- Patients awaiting heart transplantation who are at high risk for lethal arrhythmias
- Newly diagnosed nonischemic cardiomyopathy
- Peripartum cardiomyopathy.

**Temporary Contraindications to ICD**
Contraindications to an ICD are few. According to the American College of Cardiology and American Heart Association 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. It is not known how many patients refuse an ICD implantation after it has been recommended for them.

A few patients meet established criteria for an ICD (see evidence review 7.01.44) but have a transient (ie, short-term) contraindication for an implantable device. The most common contraindication is an infectious process that precludes insertion or when an ICD is removed due to infection, and there must be a delay before reinsertion to treat the infection. The WCD may benefit this group, if the device can successfully detect and abort ventricular arrhythmias in this population. The study by Tanawuttiwat et al (previously referenced) provides some direct
evidence that the WCD can be successful, but its success may be limited by nonadherence, given that 3 of the 97 patients in the study died outside of the hospital while not wearing the WCD.

The WCD avoids potential complications associated with ICD implantation, but complication rates with current techniques for ICD placement are low. In 1 large trial comparing ICD to antiarrhythmic drug therapy, complications of ICD implantation in 507 patients included hematomas in 13 (2.6%), bleeding requiring transfusion or reoperation in 6 (1.2%), infection in 10 (2.0%), pneumothorax in 8 (1.6%), and cardiac perforation in 1 (0.2%). Early mortality (≤30 days of surgery) was not higher for the ICD group (2.4%) than for the medication group (3.5%).

**Immediate Post-MI Period**

Evidence on the use of a WCD as a bridge to permanent ICD placement was reviewed in a 2010 TEC Assessment. The most common of these indications is for patients in the immediate post-MI period. 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 to prevent SCA.

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. Evaluation of 1 post hoc analysis of an RCT and 2 prospective RCTs led to this conclusion.

Secondary analysis of data from the MADIT-II trial evaluated whether an ICD reduces mortality in the early post-MI period. MADIT-II randomly assigned 1159 patients with prior MI and an EF of less than 30% to an ICD or control and showed an overall mortality benefit for patients treated with an ICD. The secondary analysis examined the benefit of ICD according to length of time from the original MI and showed that the benefit of ICD was dependent on the length of time since the original MI. Within the first 18 months post-MI, there was no benefit found for ICD implantation (hazard ratio [HR], 0.97; 95% confidence interval [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).

Two RCTs were specifically designed to address the question of early ICD use post-MI. The DINAMIT study evaluated the utility of an automatic ICD for this patient population. This trial randomly assigned 342 patients with an acute MI and an EF of 35% or less. The primary outcome was death from any cause, and a predefined secondary outcome was death from an arrhythmia. After a mean follow-up of 30 months, there was no difference in overall survival for the ICD group compared with control (HR=1.08; 95% CI, 0.76 to 1.55; p=0.66). There was a significant
difference for the ICD group in the secondary outcome of death from arrhythmia (HR=0.42; 95% CI, 0.22 to 0.83; p=0.009). The decrease in deaths from arrhythmias for the ICD group was offset by a corresponding increase in deaths due to nonarrhythmic cardiac causes. The authors suggested that the discrepancy in these outcomes may have arisen from the fact that patients in whom the ICD successfully aborted an arrhythmia may have eventually died from other cardiac causes (eg, progressive heart failure).

The IRIS trial was similar in design to the DINAMIT trial. This trial included 998 patients who were 5 to 31 days post-MI and had at least 1 other high-risk factor, either nonsustained VT or a resting pulse greater than 90. Patients were followed for a mean of 37 months. Results of the IRIS trial were similar to DINAMIT, with no difference in overall mortality between the ICD group (26.1%) and the control group (25.8%; p=0.76). The ICD group had a decreased rate of SCD (6.1% vs 13.2%, respectively, p=0.049), which was offset by a higher rate of non-SCD (15.3% vs 8.6%, respectively, p=0.001). This study also reported noncardiac death, which was similar for the ICD group (4.7%) and the control group (4.0%; p=0.51).

In 2013, Epstein et al reported on registry data from 8453 post-MI patients who received WCDs for risk of SCA while awaiting placement of an ICD. The WCD was worn a median length of 57 days (mean, 69 days) with a median daily use of 21.8 hours. Appropriate shocks were delivered 309 times in 133 (1.6%) patients, 91% of which were successful in resuscitating patients from ventricular arrhythmias. For shocked patients, 62% were revascularized post-MI and the left ventricular ejection fraction (LVEF) averaged 23.8% (8.8%). 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 further limiting interpretation of results.

In 2014, Uyei et al reported results of a systematic review conducted to evaluate the effectiveness of WCD use in several clinical situations, including individuals early (≤40 days) post-MI with an LVEF of 35% or less. The authors identified 36 articles and conference abstracts, most of which (n=28 [78%]) were abstracts. Four studies (Chung et al, Epstein et al, 2 conference abstracts) assessed the effectiveness of WCD use in post-MI patients. Outcomes reported were heterogeneous. For 2 studies that reported VF-/VT-related mortality, on average 0.52% (2/384) of the study population died of VF or VT over 58.3 mean 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 the course 58.3 mean days of WCD use (range, 3-146 days). Among those who experienced a VT or VF event, on average 82% (9/11) experienced successful termination of 1 or more arrhythmic events.

Patients Post CABG Surgery Who Are at High Risk for Lethal Arrhythmias
One RCT (CABG PATCH) evaluated early ICD placement in high-risk post CABG patients, selected with a low LVEF and abnormalities on signal-averaged
The trial followed patients for a mean of 32 months and reported on overall mortality. Trial results indicated no difference in overall mortality between the ICD and the control groups (HR=1.07; 95% CI, 0.81 to 1.42). No other mortality outcomes were reported. There was a higher rate of infections in the ICD group, both deep sternal infections (2.7% vs 0.4%, respectively, p<0.05) and superficial wound infections (12.3% vs 5.9%, respectively, p<0.05). The cumulative incidence of inappropriate shocks was 50% at 1 year and 57% at 2 years.

Zishiri et al performed a retrospective study of registry data to compare outcomes with or without WCD use in patients with LVEF less than 35% after CABG surgery or percutaneous coronary intervention (PCI). A national registry maintained by the device manufacturer was used to identify 809 patients treated with a WCD postdischarge, and a separate registry from the Cleveland Clinic was used to identify 4149 patients discharged without a defibrillator. At baseline, there were significant differences between groups for age, sex, LVEF, and time period of treatment. Of the 809 patients treated with WCD, 1.3% had documented appropriate defibrillation treatment for an arrhythmia. Post-CABG, 90-day mortality was 3% in patients with WCDs versus 7% without WCDs (p=0.03). Post-PCI, 90-day mortality was 2% in patients with WCDs versus 10% without WCDs (p<0.001). Adjusted long-term mortality risks, after a mean follow-up of 3.2 years, was also decreased in the WCD group (HR=0.74; 95% CI, 0.57 to 0.97; p=0.027). These differences in mortality persisted after propensity matching. However, interpretation of this registry data is difficult because patients treated with a WCD differed from patients who were not, and these differences may not have been completely eliminated through propensity matching.

In the 2014 Uyei systematic review previously described, 3 studies (Chung et al, Epstein et al, 1 conference abstract) were identified that reported outcomes for WCDs after coronary revascularization for patients with LVEF of 35% or less. Reported outcomes were heterogeneous across studies. In 1 study that reported on VT/VF-related mortality, 0.41% (1/243) of the study population died of VT or VF over the course of 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 the course of 59.8 days.

**Patients Awaiting Heart Transplantation Who Are High Risk for Lethal Arrhythmias**

Many patients awaiting heart transplantation are at high risk for lethal arrhythmias. A WCD can be used to reduce risks associated with ICD implantation or in situations where an ICD is contraindicated. In 2015, Opreanu et al analyzed a manufacturer’s database to identify patients prescribed a WCD as a bridge to heart transplantation. The registry included 121 patients, 12% with New York Heart Association (NYHA) functional class II heart failure, 32% with NYHA class III heart failure, 34% with NYHA class IV heart failure, and 21% unknown. Of the 121 patients, 73% were being evaluated for heart transplantation or were on a heart transplantation waiting list, and 27% were awaiting retransplantation following
rejection of a prior heart transplantation. Patients wore the WCD for a median of 20 hours per day for a median of 39 days. Seven (6%) patients received appropriate WCD shocks during this period and survived. Two patients received inappropriate shocks. Thirteen (11%) patients ended WCD use after heart transplantation, 42% ended WCD use after ICD implantation, and 15% ended WCD use after EF improved. There were 11 (9%) deaths; 9 of these patients were not wearing a WCD at the time of death. The 2 patients who died while wearing the WCD had asystole.

Patients awaiting transplantation have also been included in studies with mixed populations. The WEARIT/BIROAD study (discussed previously) assessed a prospective cohort that included patients awaiting transplant, but it also included other high-risk patients and did not report separately on the population of patients awaiting transplant. Rao et al published a case series of 162 patients with congenital structural heart disease or inherited arrhythmias treated with WCD. 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 duration of WCD treatment of approximately 1 month, but none was related to cardiac causes. Two patients received a total of 3 appropriate shocks for VT or VF, and 4 patients received a total of 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.

**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. A post hoc analysis of the DEFINITE trial, which evaluated use of an ICD in nonischemic dilated cardiomyopathy, examined the benefit of ICD use by time since diagnosis. 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. For the overall DEFINITE trial, there was a 35% reduction in overall mortality, but this difference was not statistically significant. In reanalysis, patients were divided into recent diagnosis of cardiomyopathy (<3 months) and remote diagnosis (>9 months). 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).

The WEARIT-II registry included 927 patients with nonischemic cardiomyopathy who were prescribed a WCD. At the end of the evaluation period, an ICD was implanted in 36% of patients. In 42% of patients, EF improved during the trial period, negating the need for an ICD. Another 22% of patients did not receive an ICD for other reasons.
Another potential indication for the WCD is in situations where the cardiomyopathy is reversible, but temporary protection against arrhythmias is needed. For example, this may occur in patients with alcoholic cardiomyopathy who abstain from alcohol. Salehi et al identified 127 patients from a manufacturer’s database with nonischemic cardiomyopathy possibly related to alcohol use. 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. During this period, 7 patients received 9 appropriate shocks and 13 patients received 18 inappropriate shocks. 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, 1 while wearing the WCD (due to ventricular asystole).

Kao et al reported on a prospective registry of 82 heart failure patients who were eligible for a WCD. Dilated cardiomyopathy and EF less than 40% were diagnosed in 81 (98.8%) of patients and cardiac transplantation was indicated for 12 patients. During the study, the WCD was worn for 75 (58) days, during which time no SCDs or deaths occurred. Improvement was reported in 41.5% of patients who no longer met criteria for defibrillator use. ICD placement was reported in 34.1% of patients, and 1 patient received a heart transplant. As noted above, 13 patients (16%) did not wear the WCD (due to refusal, discomfort, other/unknown reasons).

The 2014 Uyei et al systematic review previously described identified 4 studies (Saltzberg et al, Chung et al, 2 conference abstracts) that assessed WCD use in newly diagnosed nonischemic cardiomyopathy. In the 3 studies that reported VT/VF incidence, an average 0.57% (5/871) subjects experienced VT and/or VF over a mean duration of 52.6 days. Among those who did experience a VT or VF event, an average of 80% experienced successful event termination.

**Peripartum Cardiomyopathy**

One study of WCD use in peripartum cardiomyopathy was published in 2012. This study included 107 women with peripartum cardiomyopathy treated with a WCD device from 2003 through 2009. Patients were identified from a registry of WCD use maintained by a device manufacturer. WCD were worn for an average of 124 days. During this time, no shocks were delivered, either appropriate shocks or inappropriate shocks. There were no patient deaths during the time of WCD treatment. Following discontinuation of the WCD, there were 3 deaths over a mean follow-up of 3.0 (1.2) years. In a matched group of 159 women with nonischemic cardiomyopathy who wore the WCD for 96 (83) days, there were 2 appropriate shocks and 11 deaths.

In a smaller study reported in 2014, Duncker et al reported 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 LVEF of 35% or less and 7 of them consented to wear the WCD. For these 7 patients, the 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: WCD as Bridge to ICD, Heart Transplant, or Recovery**
For patients who require an ICD but have temporary contraindications for implantation, temporary use of a WCD is likely to improve outcomes. 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.

Two RCTs of ICD use in the early postacute MI period concluded that mortality did not improve compared with usual care. In both these trials, SCD was reduced in the ICD group, but in non-SCD increased, resulting in no difference in overall mortality. One trial of high-risk post-CABG patients also reported no benefit from implantation of a permanent ICD. Because a permanent ICD does not appear to be beneficial in these situations, a WCD would also not be beneficial for these patient populations.

For other indications, evidence is lacking on the impact of a WCD on outcomes. Case series for these conditions are not sufficient to determine whether a WCD improves outcomes compared with usual care.

**External Automatic Cardiac Defibrillators**
Home use of an automatic external cardiac defibrillator is another potential alternative to an ICD or a WCD. However, there are no clinical trials that establish the efficacy of automatic external defibrillators for high-risk patients. Bardy et al randomly assigned 7001 patients with anterior wall MI, who were not candidates for ICD implantation, to home external defibrillator or usual care. After a median follow-up of 37.3 months, there was no difference in mortality between groups (HR=0.97; 95% CI, 0.81 to 1.17). Therefore, home external defibrillators may not be a good alternative to ICD or WCD for high-risk patients.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 1.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01326624a</td>
<td>Study of the Wearable Defibrillator In Heart-Failure Patients</td>
<td>25</td>
<td>Mar 2016 (ongoing)</td>
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<tr>
<td>NCT02188147a</td>
<td>Ambulatory Post-Syncope Arrhythmia Protection Feasibility Study Protocol</td>
<td>80</td>
<td>Mar 2016 (ongoing)</td>
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<tr>
<td>NCT01446965a</td>
<td>Prevention of Sudden Death After Myocardial Infarction Using a LifeVest Wearable Cardioverter-defibrillator</td>
<td>1900</td>
<td>Dec 2017</td>
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<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01448005a</td>
<td>Post-market Release Registry of Wearable Defibrillator Use in Patients With Ventricular</td>
<td>69</td>
<td>Oct 2014 (terminated)</td>
</tr>
</tbody>
</table>
Dysfunction Following CABG Surgery

| NCT02122549^a | Hospital Wearable Defibrillator Inpatient Study | 59 | Jul 2015 (completed) |

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

For individuals who have a temporary contraindication for an implantable cardioverter defibrillator (ICD) who receive a wearable cardioverter defibrillator (WCD), the evidence includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The available data establish that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. 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. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence has shown that these patients benefit from a cardioverter defibrillator in general, and the WCD can detect and treat lethal arrhythmias in these patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For the immediate post myocardial infarction period, the evidence does not support the conclusion that the WCD improves outcomes. Two RCTs have reported that overall survival did not improve after treatment with a permanent ICD. While these 2 trials both reported a decrease in sudden cardiac death (SCD), there was a corresponding increase in non-SCD, resulting in no net survival benefit. Similarly, for high-risk post coronary artery bypass graft patients, 1 RCT reported no difference in overall survival associated with early ICD placement. Thus, given the lack of evidence that a permanent ICD improves outcomes for these indications, a WCD is not expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are post coronary artery bypass graft surgery and at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, or have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes case series and registry data. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment–related morbidity. It is not possible to conclude from the available evidence that the WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.
Clinical Input Received 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 7 academic medical centers and 2 physician specialty societies while this policy was under review in 2014. Input related to the role of WCDs in preventing 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 8 academic medical centers and 3 physician specialty societies 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 MI or in newly diagnosed cardiomyopathy. However, reviewers acknowledged the lack of evidence for benefit and that available evidence was not consistent in defining high-risk subgroups that may benefit.

2010 Input
In response to requests, input was received from 4 academic medical centers and no physician specialty societies while this policy was under review in 2010. Most, but not all, providing comment suggested that the WCD may have a role in selected high-risk patients following acute MI or in newly diagnosed cardiomyopathy.

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

Practice Guidelines and Position Statements

American College of Cardiology, American Heart Association, et al
Guidelines from the major cardiology specialty societies do not make specific recommendations for the use of WCD. For example, 2006 American College of Cardiology (ACC) and American Heart Association (AHA) guidelines on the treatment of patients with ventricular arrhythmias includes the following statement on WCD but does not include a formal recommendation: “The wearable automatic defibrillator has been approved in the United States by the FDA [Food and Drug Administration] for cardiac patients with a transient high risk for VF [ventricular fibrillation] such as those awaiting cardiac transplantation, those at
very high risk after a recent MI [myocardial infarction] or an invasive cardiac procedure, or those requiring temporary removal of an infected implanted defibrillator for antibiotic therapy. In 2014, the Heart Rhythm Society, ACC, and AHA issued a consensus statement on the use of ICD therapy in patients who are not included or not well-represented in clinical trials. The statement does not contain formal recommendations on WCD use, but states: “The wearable cardioverter-defibrillator (WCD) may be an option as a ‘bridge to ICD’ for selected patients at high risk of sudden cardiac death due to ventricular arrhythmias, although the data are scant.”

In 2014, ACC and AHA issued guidelines on the management of non-ST-elevation acute coronary syndrome (NSTE-ACS). These guidelines do not make specific recommendations regarding the use of WCDs, but do state the following:

“Life-threatening ventricular arrhythmias that occur >48 hours after NSTE-ACS are usually associated with LV [left ventricular] dysfunction and signify poor prognosis. RCTs [randomized controlled trials] in patients with ACS [acute coronary syndrome] have shown consistent benefit of implantable cardioverter-defibrillator therapy for survivors of VT [ventricular tachycardia] or VF [ventricular fibrillation] arrest. For other at-risk patients, especially those with significantly reduced LVEF [left ventricular ejection fraction], candidacy for primary prevention of sudden cardiac death with an implantable cardioverter-defibrillator should be readdressed ≥40 days after discharge. A life vest may be considered in the interim.”

International Society for Heart and Lung Transplantation
In 2006, the International Society for Heart and Lung Transplantation issued guidelines for the care of cardiac transplant candidates that addressed use of ICDs or WCDs. Recommendations related to the use of WCDs include:

- Class I recommendations: “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 (Level of Evidence: C).”
- Class IIa recommendations: “It is reasonable to consider placement of a defibrillator in patients with Stage D failure who are candidates for transplantation or LVAD [left ventricular assist device] destination therapy (see subsequent considerations for mechanical circulatory support device [MCSD] referral: bridge or destination) (Level of Evidence: C).”

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

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
References


3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Wearable cardioverter-defibrillator as a bridge to implantable cardioverter-defibrillator treatment. TEC Assessments. 2010;Volume 25, Tab 2.


10. Goldenberg I KH, Zareba W et al. Eighteen Month Results From The Prospective Registry And Follow-up Of Patients Using The Lifevest Wearable Defibrillator (WEARIT-II Registry) - LB02-02. Heart Rhythm 2013 - 34th Annual Scientific Sessions; May 10, 2013.


**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**

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I42.0-</td>
<td>Cardiomyopathy code range</td>
</tr>
<tr>
<td>I43</td>
<td>Cardiomyopathy code range</td>
</tr>
<tr>
<td>I47.0-</td>
<td>Paroxysmal tachycardia code range</td>
</tr>
<tr>
<td>I47.9</td>
<td>Paroxysmal tachycardia code range</td>
</tr>
<tr>
<td>I49.01-</td>
<td>Ventricular fibrillation and flutter code range</td>
</tr>
<tr>
<td>I49.02</td>
<td>Ventricular fibrillation and flutter code range</td>
</tr>
<tr>
<td>I50.1-</td>
<td>Heart failure code range</td>
</tr>
<tr>
<td>I50.9</td>
<td>Heart failure code range</td>
</tr>
<tr>
<td>Z86.74</td>
<td>Personal history of sudden cardiac arrest</td>
</tr>
</tbody>
</table>

**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.
- **12/1/12**: 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.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in
determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.