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.

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
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

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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 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 1 RCT evaluating early ICD placement after coronary artery bypass graft, and case series and registry data for other indications. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, when a WCD is used as bridge to recover, 1 RCT reported no difference in overall survival associated with early ICD placement. For other indications, the WCD is used as a bridge to heart transplant or a bridge to recovery or to permanent ICD placement, the available evidence to, 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, during which time a conscious patient can abort or delay the shock.

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 originally created in April 2003 and has been updated with regularly with searches of the MEDLINE database. The most recent literature update was conducted through March 23, 2017.

Assessment of efficacy for a therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for
this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

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) placement can provide indirect evidence on the efficacy of the WCD if the indications for a permanent ICD are similar to the 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 adults at risk for sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD.1 Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA.2 The potential indications include:

- Bridge to transplantation (ie, the WEARIT study population)
- Bridge to implantable device or clinical improvement (ie, the BIROAD study 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 (MI) with ventricular arrhythmias within 48 hours
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

**WCD Effectiveness vs ICD Effectiveness**

Very few peer-reviewed studies have reported on clinical outcomes for 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 that the evidence was sufficient to conclude that the WCD can successfully terminate malignant ventricular arrhythmias.3 Assessment conclusions were based on several factors. First, there is a strong physiologic rationale for the device. It is known that sensor leads placed on the skin can successfully detect and characterize arrhythmias. It is also established that a successful countershock can be delivered externally. The use of external defibrillators is extensive, ranging from in-hospital use to public 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 1998 case series (15 patients) of survivors of SCA 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 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 and VF.

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

The WEARIT and 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 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 implies that a relatively high rate of nonadherence may be the main factor limiting the effectiveness of the WCD. Also, there was a fairly high dropout rate (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 (2013) 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 (2012) reported that 13 patients...
did not wear the WCD due to refusal, discomfort, or other/unknown reasons. These results suggest 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.

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. 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 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 had improved. Follow-up of clinical outcomes continued through 12 months; results have been presented in abstract form but no peer reviewed publications were identified as of the most recent update.

Section Summary: WCD Effectiveness vs 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 percentage 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 device use and/or nonadherence. A more recent registry study have reported a high compliance rate when used as a trial for ICD placement, though 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 is likely to be inferior to a permanent ICD.

WCD as a 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. In addition, it can be used for any specific indication where an ICD would be used but when the ICD has been explanted or cannot be implanted due to a temporary contraindication, such as an infection. The specific indications addressed herein are:
Temporary contraindications to ICD

Immediate post 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 an ICD

Contraindications to an ICD are few. According to the 1998 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 placement after it has been recommended.

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 placement, but complication rates with current techniques for ICD placement are low. In 1 large trial (1997) comparing ICD to antiarrhythmic drug therapy, complications of ICD placement 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 postsurgery) was not higher for the ICD group (2.4%) than for the medication group (3.5%).

Section Summary: Temporary Contraindications to an ICD

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 have concluded that mortality did not improve compared with usual care. In both 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.

**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. The RCT evidence and studies published subsequently is briefly summarized here.

Secondary analysis of data from the MADIT-II trial evaluated whether an ICD reduces mortality in the early post-MI period. MADIT-II randomized 1159 patients with prior MI and an EF of less than 30% to an ICD or to 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 placement (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 early ICD use post-MI. The DINAMIT study evaluated the utility of an automatic ICD for this patient population. This trial randomized 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. Trialists suggested that the discrepancy in these outcomes might have arisen from the fact that patients in whom the ICD successfully aborted an arrhythmia might have eventually died from other cardiac causes (eg, progressive heart failure).
The IRIS trial was similar in design to the DINAMIT trial. The IRIS 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 beats per minute. 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%; p=0.049), which was offset by a higher rate of non-SCD (15.3% vs 8.6%; p=0.001), all respectively. 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 ICD placement. The WCD was worn a median 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 making interpretation of results difficult.

In 2014, Uyei et al (2014) reported 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. Reviewers identified 36 articles and conference abstracts, most of which (n=28 [78%]) were abstracts. 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 WD 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.

**Section Summary: Immediate Post-MI Period**

Two RCTs of ICD use in the early postacute MI period concluded that mortality 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. 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 CABG Surgery at High Risk for Lethal Arrhythmias**

One RCT (CABG Patch) has evaluated early ICD placement in high-risk post-CABG patients with a low LVEF and abnormalities on signal-averaged
This 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 were a higher rates of infections in the ICD group, both deep sternal infections (2.7% vs 0.4; p<0.05) and superficial wound infections (12.3% vs 5.9%; p<0.05), all respectively. The cumulative incidence of inappropriate shocks was 50% at 1 year and 57% at 2 years.

Zishiri et al (2013) retrospectively studied registry data to compare outcomes with or without WCD use in patients with a 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 U.S. registry 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 these registry data is difficult because patients treated with a WCD differed from patients not treated, and these differences might 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 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.

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

For high-risk post CABG patients, the evidence includes 1 RCT and registry studies. The 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 would not be expected to improve outcomes.

**Patients Awaiting Heart Transplantation at 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 placement or when ICD placement is contraindicated. In 2015, Opreanu et al (2015) 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 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 placement, 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 participated in studies with mixed populations. The 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. Rao et al (2011) 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 WCD treatment duration of approximately 1 month, but none was related to cardiac causes. Two patients received 3 appropriate shocks for VT or VF, and 4 patients received 7 inappropriate shocks. The results of this series suggested that the WCD can be worn safely and can detect arrhythmias in this population, but the rate of inappropriate shocks was relatively high.

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

For patients awaiting heart transplantation who are at high risk for lethal arrhythmias, evidence includes a registry and a prospective cohort. 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.

A 2006 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 placed 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 (2016) 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, only 1 while wearing the WCD (due to ventricular asystole).

The 2014 Uyei systematic review (previously described) 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.

**Section Summary: Newly Diagnosed Nonischemic Cardiomyopathy**
For patients with newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT and registries. The RCT found that prophylactic ICD placement in nonischemic cardiomyopathy was not associated with a lower rate of death than usual clinical 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**
A registry study of WCD use in peripartum cardiomyopathy was published by Saltzberg et al 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.26 A WCD was recommended for 9 patients with a LVEF of 35% or less and 7 of them consented to wear the WCD. For these 7 patients, median WCD wearing time was 81 days (mean, 133 days). In 3 patients, 4 episodes of VF were detected that led to delivery of a shock, which successfully terminated the arrhythmia in all cases. No inappropriate shocks were delivered. Among the 5 patients without WCD, no episodes of syncope or ventricular arrhythmia or deaths occurred.

Section Summary: Peripartum Cardiomyopathy
For peripartum cardiomyopathy, evidence includes a registry and small (N=7) prospective cohort. 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. Additional study is needed to determine whether the WCD is effective in preventing SCD when used as a bridge to ICD placement or recovery in this population.

Summary of Evidence

Temporary Contraindications
For individuals who have a temporary contraindication to 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 have established 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. Studies have shown that these patients benefit from a cardioverter defibrillator in general, and the WCD can detect and treat lethal arrhythmias in them. 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. 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 a conclusion that the WCD improves outcomes. Two RCTs have reported that overall survival did not
improve after treatment with a permanent ICD. While both trials reported a decrease in sudden cardiac death (SCD), there was a corresponding increase in non-SCD events, resulting in no net survival benefit. 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 1 RCT evaluating early ICD placement after coronary artery bypass graft, and case series and registry data for other indications. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, when a WCD is used as bridge to recover, 1 RCT reported no difference in overall survival associated with early ICD placement. For other indications, the WCD is used as a bridge to heart transplant or a bridge to recovery or to permanent ICD placement, the available evidence to, 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.

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

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 MI 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 and Heart Rhythm Society
In 2016, the American Heart Association (AHA) published a scientific advisory on the wearable cardioverter defibrillator (WCD). 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 1.

Table 1. Guidelines for WCD Therapy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“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.”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>“Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>“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.”</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>“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.”</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>“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.”</td>
<td>III</td>
<td>C</td>
</tr>
</tbody>
</table>

AHA: American Heart Association; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.
Heart Rhythm Society, American College of Cardiology, and American Heart Association

In 2014, the Heart Rhythm Society, American College of Cardiology (ACC), and AHA issued a joint consensus statement on the use of ICD therapy in patients who are not included or not well-represented in clinical trials. The statement did not contain formal recommendations on WCD use, but stated: “The wearable cardioverter-defibrillator (WCD) may be an option as a ‘bridge to ICD [implantable cardioverter defibrillator]’ 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 did not make specific recommendations on the use of WCDs, but indicated:

“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 are provided in Table 2.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“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.”</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>“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).”</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 (NCD). In the absence of an NCD, 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 3.

Table 3. 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>Prevention of Sudden Death After Myocardial Infarction Using a LifeVest Wearable Cardioverter-defibrillator</td>
<td>1900</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT01446965a</td>
<td>EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Denotes industry-sponsored or cosponsored trial.

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**

<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></td>
</tr>
<tr>
<td>I47.0-</td>
<td>Paroxysmal tachycardia code range</td>
</tr>
<tr>
<td>I47.9</td>
<td></td>
</tr>
<tr>
<td>I49.01-</td>
<td>Ventricular fibrillation and flutter code range</td>
</tr>
<tr>
<td>I49.02</td>
<td></td>
</tr>
<tr>
<td>I50.1-</td>
<td>Heart failure code range</td>
</tr>
<tr>
<td>I50.9</td>
<td></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.

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.

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