Wearable Cardioverter-Defibrillators

Policy Number: 2.02.15
Origination: 10/1988

Last Review: 12/2013
Next Review: 12/2014

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 all other indications including:

- 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

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

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.

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 policy No. 7.01.44 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."

Rationale

This policy was created in 2003 and updated with periodic literature reviews, the most recent covering the period between August 2012 and August 2013.

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) of WCD compared to standard care or alternative treatments. Randomized controlled trials 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.

FDA-labeled indications for the device are adult patients who are at risk for sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD. (1) Some experts (2) have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. These potential indications include:

- Bridge to transplantation (i.e., the WEARIT population)
- Bridge to implantable device or clinical improvement (i.e., the BIROAD population)
    - Postbypass with ejection fraction less than 30%
    - Postbypass with ventricular arrhythmias or syncope within 48 hours of surgery
    - Postmyocardial infarction with ejection fraction less than 30%
    - Postmyocardial 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

Is the WCD effective in detecting and terminating ventricular arrhythmias for high-risk patients, compared to an implantable device?

There are very few peer-reviewed published studies that report on clinical outcomes of WCDs and no studies that evaluate the efficacy of WCD in reducing mortality compared to alternatives. Despite the small amount of evidence, a TEC Assessment completed in 2010 (3) concluded that the evidence is sufficient to conclude that the WCD can successfully terminate malignant ventricular arrhythmias. 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 counter shock can be delivered externally. The use of external defibrillators is extensive, ranging from in-hospital use to public placement and use at home. The novelty of this device is in the way that it is packaged and utilized.

Second, there is a small amount of evidence that supports that the device successfully terminates arrhythmias. Two uncontrolled studies were identified that directly tested the efficacy of the WCD. The first (4) was a small case series of 15 patients who were survivors of SCA and 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.

The WEARIT/BIROAD study (5) was a prospective cohort study that evaluated 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. A total of 289 patients were enrolled and 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 use and compliance with the device. Six patients suffered SCA that was 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 approximately 3 months of follow-up. In a study of 134 consecutive, uninsured patients with cardiomyopathy and a mean ejection fraction of 22.5% + 7.3%, Mitrani et al., reported noncompliance with a WCD was even greater. The dropout rate was 35%. (6) The WCD was never used by 8 patients and only 27% wore the device for more than 90% of the day. Patients who were followed for 72 + 55 days wore the WCD for a mean of 14.1 + 8.1 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 and colleagues reported 13 patients (15.9%) did not wear the WCD due to refusal, discomfort or other/unknown reasons. (7) 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.

Conclusions. There are no studies that directly compare the performance of a WCD with a permanent ICD. One small study in the 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 non-adherence and dropouts, and failures to successfully resuscitate were largely attributed to incorrect use of the device and/or non-adherence. Other studies have also reported high rates of non-adherence. This evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that the overall performance in clinical care is likely to be inferior to a permanent ICD.

Does the WCD improve outcomes when used as a bridge to permanent ICD placement or clinical improvement in the following situations, compared to usual care?
- *Temporary contraindications to implantable cardioverter-defibrillator*
- *Immediate post-myocardial infarction (MI) period*
- *High-risk patients post-CABG* [coronary artery bypass graft] *surgery*
- *High-risk patients awaiting heart transplantation*
- *Newly diagnosed non-ischemic cardiomyopathy*
- *Peripartum cardiomyopathy*

Temporary contraindications to implantable cardioverter-defibrillator

Contraindications to an ICD are few. According to the American College of Cardiology/American Heart

Association/ (ACC/AHA) guidelines on ICD use, the device is contraindicated in patients with terminal illness, with drug-refractory class IV heart failure, who are not candidates for transplantation, and in patients with a history of psychiatric disorders that interfere with the necessary care and follow-up postimplantation. (8) It is not known how many patients refuse an ICD after it has been recommended for them.

There is a small number of patients who meet established criteria for an ICD (see policy No. 7.01.44) but have a transient (i.e., 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 have benefit in this group, if the device is able to successfully detect and abort ventricular arrhythmias in this population.

The WCD avoids potential complications associated with ICD implantation, but complication rates with current techniques for ICD placement are low. In 1 large trial of ICD versus antiarrhythmic drug therapy, (9) 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 (within 30 days of procedure) was not higher for the ICD group (2.4%), compared to the medication group (3.5%).

Immediate post-MI period
The evidence on the use of a WCD as a bridge to permanent ICD placement was reviewed in a 2010 TEC Assessment. (3) The most common of these indications is for patients who are in the immediate post- myocardial infarction (MI) period. For these patients, indications for a permanent ICD cannot be reliably assessed immediately post-MI, since it is not possible to determine the final ejection fraction until at least 30 days after the event. Since the first 30 days following an acute MI represent a high-risk period for lethal ventricular arrhythmias, there is a potential to improve mortality by 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. One post-hoc analysis of an RCT and 2 prospective RCTs was reviewed that led to this conclusion.

Secondary analysis of data from the MADIT-II trial evaluated whether an ICD improves mortality in the early post-MI period. (10) MADIT-II randomly assigned 1,159 patients with prior MI and an ejection fraction 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]: 0.51-1.81, 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: 0.39-0.78, p=0.001).

Two RCTs were specifically designed to address the question of early ICD use post-MI. The DINAMIT study (11) evaluated the utility of an automatic ICD (AICD) for this patient population. This trial randomly assigned 342 patients with an acute MI and an ejection fraction 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 to control (HR: 1.08; 95% CI: 0.76-1.55, 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: 0.22-0.83, 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 suggest that the discrepancy in these outcomes may arise from the fact that patients in whom the ICD successfully aborted an arrhythmia may have eventually died from other cardiac causes, such as progressive heart failure.

The IRIS trial (12) was similar in design to the DINAMIT trial. This study included 998 patients who were 5 to 31 days post-MI and had at least 1 other high-risk factor, either nonsustained ventricular tachycardia 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 and control groups (26.1% vs. 25, respectively.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 nonsudden cardiac death (15.3% vs. 8.6%, respectively, p=0.001). This study also reported noncardiac death, which was similar for the ICD and control groups (4.7% vs. 4.0%, respectively, p=0.51).

In 2013, Epstein and colleagues reported on registry data from 8,453 post-MI patients who received WCDs for risk of sudden cardiac arrest while awaiting placement of an ICD. (13) The WCD was worn a median length of 57 days (mean length of 69 + 61 days) with a median daily use of 21.8 hours. Appropriate shocks were delivered 309 times in 133 patients (1.6%), 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.

High-risk patients after coronary revascularization
One randomized controlled trial (CABG PATCH) (14) evaluated early ICD placement in high-risk postcoronary artery bypass graft surgery (CABG) patients, selected by a low LVEF and abnormalities on signal-averaged electrocardiogram (EKG). The trial followed patients for a mean of 32 months and reported on overall mortality. Results of this trial indicated no difference in overall mortality between the ICD and control groups (HR: 1.07; 95% CI: 0.81–1.42). There were no other mortality outcomes 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 and colleagues performed a retrospective study that used registry data to compare outcomes with or without WCD use in patients with LVEF <35% after CABG surgery or percutaneous coronary intervention (PCI). (15) A national registry maintained by the manufacturer was used to identify 809 patients treated with a WCD post-discharge, and a separate registry from the Cleveland Clinic was used to identify 4,149 patients discharged without a defibrillator. At baseline, there were significant differences between groups on age, gender, 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<0.0001). 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: 0.57-0.97, p=0.027). These differences in mortality persisted after propensity matching. However, interpretation of this registry data is limited since patients treated with a WCD differed from patients who were not treated, and these differences may not have been completely eliminated through propensity matching. Therefore, this evidence is not sufficient to determine whether WCDs improve outcomes post coronary revascularization.

High-risk patients awaiting heart transplantation
There are no studies that specifically address this population of patients, but some patients awaiting transplantation have been included in studies with mixed populations. The WEARIT/BIROAD study, discussed previously, was a prospective cohort study 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. (5) Rao et al. (16) published a case series of 162 patients with either 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.

There were 4 patient deaths during a mean duration of WCD treatment of approximately 1 month, but none of these were related to cardiac causes. Two patients received a total of 3 appropriate shocks for VT/ VF, and 4 patients received a total of 7 inappropriate shocks. The results of this study suggest that the WCD can be worn safely and can detect arrhythmias in this population, but the rate of inappropriate shocks is relatively high.

Newly diagnosed non-ischemic cardiomyopathy
Another potential indication for the WCD is in patients with newly diagnosed nonischemic cardiomyopathy. Similar to acute MI, in these patients the final ejection fraction is uncertain, since some patients who are newly diagnosed with nonischemic cardiomyopathy show an improvement in ejection fraction over the ensuing several months. A post-hoc analysis of the DEFINITE trial, (17) which evaluated the 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 did not meet statistical significance. In the re-analysis, patients were divided into recent diagnosis of cardiomyopathy (less than 3 months) and remote diagnosis (greater than 9 months). The difference in survival was of borderline significance for the ICD group compared to controls, both for the recently diagnosed subgroup (HR: 0.38; 95% CI: 0.14–1.00, p=0.05), and the remotely diagnosed subgroup (HR: 0.43; 95% CI: 0.22–0.99, p=0.046).

Kao et al. reported on a prospective registry of 82 heart failure patients who were eligible for a WCD. (7) Dilated cardiomyopathy and ejection fraction (EF) <40% were diagnosed in 98.8% of patients and cardiac transplantation was indicated for 12 patients. During the study, use of the WCD was 75 + 58 days during which time, no SCDs or deaths occurred. Improvement was reported in 41.5% of patients who no longer met the criteria for defibrillator use. ICD placement was reported in 34.1%.of patients and one patient received a heart transplant. As noted above, 13 patients (15.85%) did not wear the WCD due to refusal, discomfort or other/unknown reasons

Peripartum cardiomyopathy
One study of WCD use in peripartum cardiomyopathy was published in 2012. (18) This study included 107 women with peripartum cardiomyopathy treated with a WCD device during the period of 2003 through 2009. Patients were identified from a registry of WCD use maintained by the manufacturer of the device. The average length of time that the WCD was used was 124+123 days. During this time, there were no shocks delivered, either appropriate shocks or inappropriate shocks. There were also 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 non-ischemic cardiomyopathy who wore the WCD for 96+83 days, there were 2 appropriate shocks and 11 deaths.

Conclusions. For patients with indications for an ICD but temporary contraindications, the use of a WCD for a temporary period of time is likely to improve outcomes. These patients are expected to benefit from an ICD, and the use of a WCD is a reasonable alternative as there are no other options for automatic detection and termination of ventricular arrhythmias.

Two RCTs of implantable cardioverter-defibrillator use in the early post-acute MI period concluded that mortality was not improved compared to usual care. In both these trials, sudden cardiac death was reduced in the ICD group, but non-sudden cardiac death was 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. Since 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 concerning the impact of a WCD on outcomes. Case series for these conditions are not sufficient to determine whether a WCD improves outcomes compared to usual care.

External automatic cardiac defibrillators

Home use of an automatic external cardiac defibrillator is another potential alternative to either an ICD or a wearable defibrillator. However, there are no clinical trials that establish the efficacy of automatic external defibrillators for high-risk patients. Bardy et al. (19) randomly assigned 7,001 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: 0.81-1.17). Therefore, home external defibrillators may not be a good alternative to ICD or WCD in high-risk patients.

Ongoing trials
A search of online site ClinicalTrials.gov on September 16, 2013 using the terms wearable cardioverter defibrillator returned a total of 3 ongoing trials. One of these is an RCT, which is described further below.

- Vest Prevention of Sudden Death Trial (NCT01446965). This is an unblinded RCT comparing WCD treatment to usual care in patients with recent MI and LV ejection fraction <35%. The primary outcome measure is mortality due to sudden death. Secondary outcomes are all-cause mortality, cardiovascular mortality, other cause-specific mortality, incidence of ventricular arrhythmias, adverse events due to the WCD, and compliance with the device. Estimated study enrollment is 1,900 patients, and study completion date is listed as September 2015.

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.

2008
In response to the request for input through Physician Specialty Societies and Academic Medical Centers, no input was received while this policy was under review for the April 2008 update.

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

2013
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, of those providing input suggested that the wearable defibrillator may have a role in selected high-risk patients following acute myocardial infarction 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.

Summary
The available data establish that the wearable cardioverter-defibrillator (WCD) device can detect lethal arrhythmias and can successfully deliver a counter shock in most cases. There are a small number of patients who meet established criteria for an implantable cardioverter-defibrillator (ICD) but have a transient contraindication for an implantable device, most commonly an infectious process. In these patients who are scheduled for ICD placement, the WCD may be considered medically necessary as an interim treatment. The evidence shows that these patients benefit from a cardioverter-defibrillator in general; and the WCD can detect and treat lethal arrhythmias in these patients.

For other bridging indications, particularly for the immediate post-myocardial infarction period, the

evidence does not support the conclusion that the WCD improves outcomes. Two randomized controlled trials have reported that overall survival is not improved following treatment with a permanent ICD. While these two trials both reported a decrease in sudden cardiac death (SCD), there was a corresponding increase in non-SCD, resulting in no net benefit in survival. Similarly, for high-risk post-coronary artery bypass graft patients, one randomized controlled trial 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 and is therefore considered investigational.

For other potential indications, there are only case series or no relevant published evidence. Therefore it is not possible to conclude from the available evidence that net health outcome will be improved. These other indications, including bridge to transplantation, newly diagnosed non-ischemic cardiomyopathy, and peripartum cardiomyopathy, are also considered investigational.

Clinical Practice Guidelines and Position Statements
Guidelines from the major cardiology specialty societies do not make specific recommendations for the use of WCD. For example, the most recent ACC/AHA guidelines on the treatment of patients with ventricular arrhythmias (20) 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 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."

Medicare National Coverage
There is no national coverage determination.

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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

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.