APPENDIX to Wearable Cardioverter-Defibrillators Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

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.

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 WCDs compared with standard care or alternative treatments. RCTs of patients

undergoing permanent 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 a WCD and if the performance of the WCD has been shown to approximate that of a permanent ICD.

The U.S. Food and Drug Administration (FDA) approved the Lifecor WCD® 2000 system via premarket application approval in December 2001. Lifecor, Inc. was bought by Zoll Medical Corporation (Pittsburgh, PA) in 2006 and Lifecor WCD is now referred to as LifeVest®. FDA-labeled indications for the device are adult patients who are at risk for 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 (Beauregard, 2004). These potential indications include:

- Bridge to transplantation (i.e., the Wearable Defibrillator Investigative Trial [WEARIT] population)
- Bridge to implantable device or clinical improvement (i.e., the Bridge to ICD in Patients at Risk of Arrhythmic Death [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 with 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 with alternatives. Despite the small amount of evidence, a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment completed in 2010 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 countershock 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 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 of 15 patients who were survivors of SCA and scheduled to receive an ICD (Auricchio et al., 1998). 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 WCDs effectiveness for preventing sudden death based on a postmarket release registry of 3,569 patients who received a WCD. Investigators found an overall successful shock rate of 99% for VT or VF (79 of 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 2013, 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 that were 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 Wearable Defibrillator Investigative Trial/Bridge to ICD in Patients at Risk of Arrhythmic Death (WEARIT/BIROAD) study by Feldman et al. (2004) was a prospective cohort study evaluating 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. Clinical outcomes for longer term follow up for 758 patients prescribed a WCD for a transient or undefined arrhythmia risk who were prospectively enrolled in a registry have been published in abstract form (Goldenberg et al., 2013). This abstract reports that during the follow-up period, there were 15 “appropriate” shocks delivered. Details about the registry population, the patient selection process, and the outcomes are not sufficient to allow more complete evaluation of the study findings.

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. (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 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 et al. (2012) reported 13 patients (15.9%) 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.

Section Summary

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 nonadherence and dropouts, and failures to successfully resuscitate were largely attributed to incorrect use of the device and/or nonadherence. Other studies have also reported high rates of nonadherence. 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 with usual care?

- *Temporary contraindications to ICD*
- *Immediate postmyocardial infarction (MI) period*
- *High-risk patients post-CABG [coronary artery bypass graft] surgery*
- *High-risk patients awaiting heart transplantation*
- *Newly diagnosed nonischemic cardiomyopathy*
- *Peripartum cardiomyopathy*

Temporary Contraindications to ICD

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 (Gregoratos et al., 1998). 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 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 study by Tanawuttiwat et al. (2013) referenced above provides some direct evidence that the WCD can be successful, but its successful use may be limited by nonadherence, given that 3 of the 97 patients included 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 a large trial conducted by Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators (1997) of ICD versus anti-arrhythmic 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%)
- Cardiac perforation in 1 (0.2%)

Early mortality (within 30 days of procedure) was not higher for the ICD group compared to the medication group (2.4% versus 3.5%), respectively.

Immediate Post-MI Period

The evidence on the use of a WCD as a bridge to permanent ICD placement was reviewed in the 2010 TEC Assessment. The most common of these indications is for patients who are in the immediate postmyocardial infarction (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 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 Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) evaluated whether an ICD improves mortality in the early post-MI period (Wilber et al., 2004). 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 an ICD according to length of time from the original MI and showed that the benefit of an 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 Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) evaluated the utility of an automatic ICD (AICD) for this patient population (Hohnloser et al., 2004). 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 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 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 Immediate Risk Stratification Improves Survival (IRIS) trial was similar in design to the DINAMIT trial (Steinbeck et al., 2009). 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 25.8%, respectively; 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 et al. 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. The WCD was worn a median length of 57 days (mean: 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 RCT, the Coronary Artery Bypass Graft (CABG) Patch (CABG-PATCH) trial evaluated early ICD placement in high-risk post-CABG patients, selected by a low LVEF and abnormalities on signal-averaged electrocardiogram (ECG) (Bigger, 1997). 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 to 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 et al. (2013) performed a retrospective study that used 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 manufacturer was used to identify 809 patients treated with a WCD postdischarge, 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 a 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 limited because 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 (Feldman et al., 2004). Rao et al. (2011) published a case series of 162 patients with either congenital structural heart disease or inherited arrhythmias treated with a 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 Nonischemic 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 because 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 by Kadish et al. (2006) 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 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).

Kao et al. (2012) reported on a prospective registry of 82 heart failure patients who were eligible for a WCD. Dilated cardiomyopathy and ejection fraction less than 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 1 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 by Saltzberg et al. 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 nonischemic cardiomyopathy who wore the WCD for 96 (± 83) days, there were 2 appropriate shocks and 11 deaths.

In conclusion, 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 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 was not improved compared with usual care. In both these trials, sudden cardiac death was reduced in the ICD group, but nonsudden 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 with 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. (2008) 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 to 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 April 9, 2014 using the terms wearable cardioverter defibrillator returned a total of 4 ongoing trials. One of these is an RCT, which is described further below.

- Vest Prevention of Early Sudden Death Trial and VEST Registry (NCT01446965): This is an unblinded RCT comparing WCD treatment to usual care in patients with recent MI and LV ejection fraction less than 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.

Summary

The available data establish that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. There are a small number of patients who meet established criteria for an 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 postmyocardial infarction period, the evidence does not support the conclusion that the WCD improves outcomes. Two RCTs have reported that overall survival is not improved following treatment with a permanent ICD. While these 2 trials both reported a decrease in sudden cardiac death, there was a corresponding increase in non-SCD, resulting in no net benefit in survival. Similarly, for high-risk postcoronary 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 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 nonischemic 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 a WCD. For example, the American College of Cardiology/American Heart Association/European Society of Cardiology (ACC/AHA/ESC) 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, includes the following statement on WCDs 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 ventricular fibrillation (VF) such as those awaiting cardiac transplantation, those at very high risk after a recent MI or an invasive cardiac procedure, or those requiring temporary removal of an infected implanted defibrillator for antibiotic therapy (Zipes et al., 2006).

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
	93745	Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events
HCPC	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
ICD9 Procedure	None	

Type	Number	Description
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Implantable Cardioverter Defibrillator

Key / Related Searchable Words

- Cardioverter Defibrillator
- LifeCor WCD System
- LifeVest
- WCD
- Wearable Cardiac Defibrillator
- Wearable Cardioverter Defibrillator
- Wearable Vest

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
	Policy Title Revision, criteria revised	Medical Policy Committee
12/7/2006	BCBSA Medical Policy adoption	Medical Policy Committee
9/25/2009	Criteria Revised Policy title change. Prior Policy title: Wearable Cardioverter-Defibrillators for the Prevention of Sudden Cardiac Death	Medical Policy Committee
1/11/2013	Policy revision without position change	Medical Policy Committee

Effective Date	Action	Reason
7/14/2014	Policy title change from Wearable Cardioverter Defibrillator Policy revision with position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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