



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Wearable Cardioverter
Defibrillator and Automatic
External Defibrillator**

**Effective Date 1/15/2010
Next Review Date 1/15/2011
Coverage Policy Number 0431**

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Hyperlink to Related Coverage Policies

Biventricular Pacing/Cardiac
Resynchronization Therapy (CRT)
Implantable Cardioverter Defibrillator (ICD)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

Coverage for a wearable cardioverter defibrillator is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for a wearable cardioverter defibrillator is available, the following conditions of coverage apply.

CIGNA covers a wearable cardioverter defibrillator (e.g., LifeVest™) as medically necessary when EITHER of the following criteria is met:

- The individual is at high risk for sudden cardiac death and meets criteria for implantable cardioverter defibrillator (ICD) placement* but is not currently a suitable candidate for ICD placement because of one of the following:
 - awaiting heart transplantation
 - awaiting ICD reimplantation following infection-related explantation
 - systemic infectious process or other temporary medical condition precludes implantation

- As a bridge to ICD risk stratification and possible implantation for patients immediately following myocardial infarction (MI) with a history of ventricular tachycardia or ventricular fibrillation after the first 48 hours, or with a left ventricular ejection fraction ≤ 40

CIGNA does not cover an automatic external defibrillator (AED) because it is primarily considered a safety device kept in the home as a precautionary measure to address a possible acute event, rather than a device needed for active treatment. An AED in the home is therefore not considered medically necessary.

***Criteria for ICD placement (Refer to Implantable Cardioverter Defibrillator Coverage Policy for additional information):**

CIGNA covers the use of an implantable cardioverter defibrillator (ICD) as medically necessary for individuals who are receiving ongoing optimal medical therapy and ANY of the following criteria are met:

- cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT) after evaluation to define the cause of the event and to exclude any completely reversible causes
- structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.
- syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study
- left ventricular ejection fraction (LVEF) less than 35% due to prior myocardial infarction (MI), at least 40 days post-MI, in New York Heart Association (NYHA) functional Class II or III
- nonischemic dilated cardiomyopathy (DCM), LVEF less than or equal to 35%, in NYHA functional Class II or III.
- LV dysfunction due to prior MI, at least 40 days post-MI, LVEF less than 30%, in NYHA functional Class I
- nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study
- unexplained syncope, significant LV dysfunction, and nonischemic DCM.
- sustained VT, with normal or near-normal ventricular function
- hypertrophic cardiomyopathy (HCM) with one or more major risk factors for sudden cardiac death (SCD)
- arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C), with one or more risk factors for SCD.
- long-QT syndrome, experiencing syncope and/or VT while receiving beta blockers
- non-hospitalized individuals awaiting transplantation
- Brugada syndrome with syncope
- Brugada syndrome with documented VT that has not resulted in cardiac arrest
- catecholaminergic polymorphic VT with syncope and/or documented sustained VT while receiving beta blockers
- cardiac sarcoidosis, giant cell myocarditis, or Chagas disease
- symptomatic sustained VT in a child or adult with congenital heart disease who has undergone hemodynamic and electrophysiological evaluation.
- recurrent syncope of undetermined origin in a child or adult with congenital heart disease in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study

CIGNA covers the use of an ICD as medically necessary in children who are receiving optimal medical therapy and have survived cardiac arrest, after evaluation to define the cause of the event and to exclude any reversible causes.

General Background

There is a high incidence of sudden cardiac death (SCD) in patients with heart failure and diminished left ventricular ejection fraction (LVEF) and in patients who are recovering from acute myocardial infarction (MI). Although significant effort has been directed to the identification and treatment of high-risk patients, this group actually accounts for a small proportion of preventable SCD. Although the risk of SCD increases in proportion to the severity of cardiac disease in an individual patient, most events occur in patients with no known cardiac history and with few or no risk factors. There is no single test capable of accurately predicting SCD risk in various clinical settings and patient populations. Although available tests can provide valuable information, they are hampered by limited positive predictive value and are not sufficiently investigated in many categories of patients with structural heart disease (Zipes et al., 2006; Kusmirek and Gold, 2007).

Ventricular fibrillation is the rhythm most frequently recorded at the time of sudden cardiac arrest. Although a number of studies have investigated the electrophysiologic (EP) mechanisms responsible for the onset of ventricular tachycardia and ventricular fibrillation, antiarrhythmic agents have not been shown to be effective in preventing SCD. Rather, it is the drugs that have no direct EP actions on cardiac muscle or specialized conducting tissue that have been demonstrated to be effective in preventing SCD. Such drugs include beta blockers, ACE inhibitors, angiotensin receptor-blocking agents, lipid-lowering agents, spironolactone, and fibrinolytic and anti-thrombotic agents (Zipes, et al., 2006).

The implantable cardioverter defibrillator (ICD) is a surgically implanted device designed to constantly monitor an individual's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT) and deliver an electric shock to terminate these arrhythmias in order to reduce the risk of sudden death. ICDs have been demonstrated to be effective in the prevention of sudden death in patients who have experienced a life-threatening clinical event associated with sustained ventricular tachyarrhythmia, patients who have had a prior MI and reduced left ventricular ejection fraction (LVEF), and patients who have cardiac risk factors that place them at increased risk for sudden cardiac death. (Refer to Implantable Cardioverter Defibrillator Coverage Position). A wearable cardioverter defibrillator may be an option for patients who are at risk for sudden death due to cardiac arrhythmias but are not considered candidates for ICD placement.

Wearable Cardioverter Defibrillator (WCD)

U.S. Food and Drug Administration (FDA): The LIFECOR Wearable Cardioverter Defibrillator (WCD[®]) 2000 System (Lifecor, Inc., Pittsburgh, PA) was approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process on December 18, 2001. According to the FDA approval letter, the WCD 2000 System is indicated for adult patients who are at risk for sudden cardiac arrest and who are not candidates for or refuse an ICD. The device is contraindicated in patients with an active ICD and should not be used in patients who:

- need an ICD or already have an operating ICD
- are under age 18
- have a vision or hearing problem that may interfere with reading or hearing the WCD messages
- are taking medication that would interfere with pushing the response buttons on the WCD alarm module
- are unwilling or unable to wear the device continuously, except when bathing or showering
- are pregnant or breastfeeding
- are of childbearing age and not attempting to prevent pregnancy
- are exposed to excessive electromagnetic interference (EMI) from machinery such as powerful electric motors, radio transmitters, power lines, or electronic security scanners, as EMI can prevent the WCD from detecting an abnormal heart rhythm

The trade name of the WCD 2000 System was changed to LifeVest[™] in 2002. The LifeVest is a microprocessor-based and programmable patient-worn device that is designed to sense cardiac function and automatically deliver electrical therapy to treat ventricular arrhythmias. The device is intended to be worn continuously, since the purpose of the device is to constantly monitor the patient's electrocardiogram (ECG) and detect life-threatening ventricular tachyarrhythmias (i.e., VT or VF). If the device detects VT or VF above a programmable preset rate, it is capable of delivering a defibrillating pulse to the heart through the electrodes in an attempt to restore an effective rhythm. The wearable components include a monitor, battery pack, alarm module, electrode belt, garment and holster. The nonwearable components include a battery charger, modem, mode cable, computer cable, diagnostic tester, and the WCDNET. The WCDNET is a web-based data storage and retrieval system that allows physicians to access patient data using a web browser and Internet connection. An

authorized physician or operator can view and print electrocardiogram events and generate reports related to patient wear-time and overall WCD 2000 monitoring performance.

The LifeVest communicates with the patient through voice and display messages, tones, or alarms and vibration against the skin. When an arrhythmia is detected, the device instructs the patient to stop the impending shock by pressing a response button to avoid receiving a shock while conscious. The device is designed to deliver an electrical shock therapy pulse within 60 seconds of the onset of VT or VF unless a conscious patient presses the response button.

Literature Review

The prospective nonrandomized multicenter trial submitted as part of the FDA PMA for the WCD 2000 System has since been published (Feldman, et al., for the WEARIT/BIROAD Investigators, 2004). The WEARIT and BIROAD studies were designed to assess the safety and efficacy of a wearable cardioverter defibrillator in treating ventricular tachyarrhythmias in patients who were at high risk for SCD but did not meet eligibility criteria for ICD placement or who would not receive an ICD for several months. After a combined total of 289 patients had been enrolled in the two studies, prespecified safety and effectiveness guidelines had been met. Two populations of patients were selected. The WEARIT study (n=177) enrolled MYHA class III or IV patients with an ejection fraction (EF) of < 30%. The BIROAD study (n=112) enrolled patients in whom a wearable device could be used to bridge patients for a four-month period to possible ICD implantation, including those with complications associated with high risk of sudden death after an MI or bypass surgery. Six of eight defibrillator attempts were successful. Six inappropriate shock episodes occurred during 901 months of patient use. Of six sudden deaths that occurred during the study, five were in patients not wearing the device, and one occurred in a patient wearing the device incorrectly. The authors concluded that the results of these studies suggest that a wearable defibrillator is beneficial in detecting and effectively treating ventricular tachyarrhythmias in patients at high risk for sudden death who are not clear candidates for an ICD and may be useful as a bridge to transplantation or ICD in some patients. The authors acknowledged several limitations of the WEARIT/BIROAD study, including the fact that 46 patients received an ICD during the course of the study, raising the possibility that these individuals might have been less likely to have survived a defibrillation by the wearable device, and thus their early exit from the study may have biased the results. A second limitation was the fact that this study did not have a control group of patients not receiving the wearable device.

A technology assessment published by the California Technology Assessment Forum (CTAF), *Wearable Cardioverter Defibrillator for Patients at Risk for Sudden Cardiac Death*, concluded that the use of a wearable cardioverter defibrillator (WCD) for patients at risk for sudden cardiac arrest and who are not candidates for or refuse an ICD does not meet the CTAF criteria. The assessment noted that the published peer reviewed literature of the WCD in clinical practice is limited to the Feldman study (discussed above). The assessment also included uncontrolled case series by Auricchio (1998, n=15), and Reek (2003, n=12) that evaluated the ability of the device to detect and terminate tachyarrhythmias induced in the controlled setting of the electrophysiology laboratory. The author concluded that the limited scientific evidence, consisting of one pivotal trial with a precursor device and a small number of events, does not permit conclusions regarding the effectiveness of the WCD regarding health outcomes. A multicenter cohort study evaluating the impact of the WCD on mortality and quality of life in patients who meet criteria for, but are unable or unwilling to have an ICD, is needed before definitive conclusions can be made regarding safety and effectiveness. For patients who do not meet criteria for an ICD but are considered to be at increased risk of SCD (e.g., post acute MI with reduced EF), a randomized controlled trial with mortality data is recommended before the safety and efficacy of the device can be evaluated for use in clinical practice (Feldman, 2009).

An ECRI evidence report, *Wearable External Cardioverter Defibrillator for Detection and Treatment of Ventricular Arrhythmias*, was published in 2002 and updated in 2007. The report states that the WCD may provide a temporary, noninvasive alternative to ICD implantation in patients at risk for arrhythmia-related cardiac arrest; identify patients at increased risk for sudden death who may be candidates for ICD implantation; and fill a therapeutic gap between hospitalization and heart transplantation. The report concluded that multicenter controlled studies are needed to compare outcomes of different treatment options for ventricular fibrillation and sudden cardiac arrest, evaluate long-term clinical results of the WCD, optimize device design, establish the cost-effectiveness of this technology for select patient populations, and explore quality of life issues related to its use.

The safety and efficacy of ICDs are well-established for appropriately selected patients at high risk for SCD. Progressive improvements in design and miniaturization have allowed transvenous placement of an ICD, although invasive, to become a routine procedure. In contrast, there is minimal evidence in the published medical literature on the safety and efficacy of wearable defibrillators. These devices should therefore be limited to the small subset of patients at high risk for SCD who meet criteria for ICD placement but in whom the procedure is currently not indicated, such as those awaiting heart transplantation, awaiting ICD reimplantation following infection-related explantation, or patients with a systemic infectious process or other temporary condition that precludes implantation. The WCD may also be appropriate as a bridge to ICD risk stratification and possible implantation for patients in the immediate post-MI period who have either a history of ventricular tachycardia or ventricular fibrillation at least 48 hours after the acute MI, or a left ventricular ejection fraction $\leq 40\%$.

Professional Societies/Organizations

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2006 Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Zipes, et al., 2006) states that a WCD has been approved by the FDA, but use of a WCD is not included in the guideline recommendations.

The ACC/AHA/ESC Guideline for Management of Patients with ST-Elevation Myocardial Infarction (Antman, et al., 2006) states that a WCD has been developed that may be applicable for high-risk patients after ST elevation MI, but use of a WCD is not included in the guideline recommendations. A focused update of this guideline published in 2007 does not address use of a WCD.

The ACC/AHA/Heart Rhythm Society (HRS) 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein, et al.) does not address use of a WCD.

Automatic External Defibrillator (AED)

U.S. FDA: The Philips HeartStart Home OTC Defibrillator (Philips Medical Systems, Seattle, WA) received FDA approval through the 510(k) process on September 16, 2004. The previous version of the HeartStart was available by prescription only, while the HeartStart Home OTC ECD was approved for home use without a prescription. Data submitted to the FDA demonstrated that the device could be used successfully in a mock rescue by laypersons based on written instructions and the device itself. There was no evidence, however, to demonstrate that use of the device in the home by untrained persons improves outcomes.

Literature Review

Early defibrillation has been shown to be a critical factor in improving survival after out-of-hospital cardiac arrest. The use of automatic external defibrillators (AEDs) has become an important component of emergency medical services (EMS), and advances in technology have permitted expansion of AED use to minimally-trained first responders and trained laypersons who witness an arrest.

There is little published information on the efficacy of AED use in the home. The Public Access Defibrillation (PAD) Trial, a community-based prospective multicenter trial, was designed to determine whether the rate of survival would increase if laypersons are trained to attempt defibrillation with the use of AEDs. A diverse group of community facilities (e.g., shopping malls, recreation centers, hotels and apartment complexes) was recruited to participate. Each facility had to have a pool of potential volunteer responders and the ability to deliver an AED within three minutes to a person in cardiac arrest. The number of patients who survived to discharge after out-of-hospital cardiac arrest where volunteers recognized the event, telephoned EMS, and performed cardiopulmonary resuscitation (CPR) was compared to the number who survived to discharge when volunteers could also provide early defibrillation with an on-site AED. There were more survivors to hospital discharge in units assigned to have responders trained in CPR plus the use of AEDs (30 survivors/128 arrests) than in the group assigned to have volunteers trained only in CPR (15 survivors/107 arrests). When the data for arrests that occurred in residential units and public units are examined separately, however, there is no demonstrated survival benefit of CPR plus AED in residential patients. There were 37 arrests/one survivor in residential units and 70 arrests/14 survivors in public units in the group treated by CPR only, compared to 33 arrests/one survivor in the residential units and 95 arrests/29 survivors in the public units in the group treated with CPR and AED. The authors concluded that training and equipping volunteers to attempt early defibrillation within a structured response system can increase the number of survivors to hospital discharge after out-of-hospital

cardiac arrest. This study, however, does not provide evidence that AEDs in residences improve survival beyond what is achieved with standard EMS response.

The Home Automatic External Defibrillator Trial (HAT), an international, multicenter trial sponsored by the National Heart, Lung, and Blood Institute (NHLBI), was designed to test whether an AED in the home of patients with intermediate risk of sudden cardiac arrest could improve survival (Bardy et al., for the HAT Investigators, 2008). A total of 7001 patients at 178 clinical sites in seven countries were randomized between 2003 and 2005. Patients in stable medical condition who had a previous anterior-wall Q-wave or non-Q-wave MI were randomized to receive one of two responses after a cardiac arrest occurring at home: either the control response that included calling emergency medical services (EMS) and performing cardiopulmonary resuscitation (CPR) (n=3506), or the use of an AED, followed by calling EMS and performing CPR (n=3495). The primary outcome was death from any cause. Patients who were candidates for an ICD were excluded from the study. Evidence-based drug therapy was encouraged for all patients. Participants were required to have a spouse or companion willing and able to call for assistance from emergency medical services (EMS), perform CPR, and use an AED. The median follow-up was 37.3 months. A total of 450 patients died; 228 of 3506 (6.5%) in the control group and 222 of 3495 patients (6.4%) in the AED group (p=0.77). Only 160 deaths (35.6%) were considered to be from sudden cardiac arrest from tachyarrhythmia. Of these deaths, 117 occurred at home and 58 events were witnessed. AEDs were used in 32 patients; 14 received an appropriate shock, and four survived to hospital discharge. No inappropriate shocks were documented. Access to a home AED did not significantly improve overall survival in this intermediate risk population, compared to reliance on conventional resuscitation methods. The authors stated that the high proportion of unwitnessed events, the underuse of the AEDs in emergencies, rather than a lack of device efficacy, appear to explain these results.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and improved outcomes of use of an AED in the home. An AED in the home is primarily considered a safety device kept in the home as a precautionary measure to address a possible acute event, rather than a device for active treatment.

Professional Societies/Organizations

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2006 Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Zipes, et al., 2006) states that placement of AEDs in the home appears to be reasonable and appropriate for patients at high risk for life-threatening arrhythmias. The guideline recommendations, however, do not include home use of an AED.

The ACC/AHA/ESC Guideline for Management of Patients with ST-Elevation Myocardial Infarction (Antman, et al., 2006) recommendations do not include AED use in the home. A focused update of this guideline published in 2007 does not address use of an AED.

The electrical therapies section of the AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005) state that reviewers found no studies that documented the effectiveness of home AED deployment, so there is no recommendation for or against personal or home deployment of AEDs.

The ACC/AHA/Heart Rhythm Society (HRS) 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Epstein, et al.) does not address use of an AED.

Summary

The safety and efficacy of implantable cardioverter defibrillators (ICDs) is well established for appropriately selected patients at high risk for sudden cardiac death (SCD). Advances in technology have permitted ICD placement to be performed using minimally invasive techniques. In contrast, evidence in the published medical literature on the safety and efficacy of wearable defibrillators (WCDs) is limited. These devices should therefore be limited to the small subset of patients at high risk for SCD who meet criteria for ICD placement but in whom the procedure is currently not indicated, such as those awaiting heart transplantation, awaiting ICD reimplantation following infection-related explantation, or patients with a systemic infectious process or other temporary condition that precludes implantation. The WCD may also be appropriate as a bridge to ICD risk stratification and possible implantation for patients in the immediate post-MI period who have either a history of ventricular tachycardia or ventricular fibrillation at least 48 hours after the acute MI, or a left ventricular ejection fraction $\leq 40\%$.

Automatic external defibrillators (AEDs) have become an important component of emergency medical systems (EMS), and the availability of AEDs in public places is expanding. There is insufficient evidence in the published medical literature, however, to demonstrate that use of AEDs in the home by laypersons improves outcomes. An AED in the home is primarily considered a safety device kept in the home as precautionary measure to address a possible acute event, rather than a device for active treatment.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
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.

HCPCS Codes	Description
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

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
E0617	External defibrillator, with integrated electrocardiogram analysis

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

*Current Procedural Terminology (CPT[®]) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	01/15/2008	0431	Wearable Cardioverter Defibrillator and Automatic External Defibrillator
Great-West Healthcare	08/28/2006	09/21/04	Cardioverter Defibrillator, Implantable and Wearable

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