Wearable Cardio Defibrillator and Automatic External Defibrillator

Description:

A Wearable Cardioverter Defibrillator (WCD). 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 tachyarrhythmia’s (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.

Background Information:

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 ≤ 40%. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of the WCD for any other
indication, including use following coronary artery bypass graft (CABG) surgery or percutaneous coronary angioplasty (PTCA).

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.

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.

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. 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.

**Administrative Criteria:**

1. **Wearable Cardioverter Defibrillators (WCDs) may be covered under the DME benefit when interqual criteria are met.**

2. **Automatic External Defibrillators (AEDS) in the public setting or in the home are not a covered benefit.**

3. Documentation must include the following (not all inclusive):
   a. Member’s name
   b. Plan ID#
   c. Well documented medical information to support medical necessity must be submitted for review.
   d. Length of time recommended (WCD)
   e. Discharge plan and follow-up recommendations with specialist should be included with medical information submitted.
   f. Monthly monitoring reports supportive of member compliance with WCD
   g. Specialist should be in-network provider
   h. Prior Authorization from the health plans UM department (inpatient stay) recommended prior to placement of the WCD
   i. Member must have current eligibility on Date of Service

**Clinical Criteria:**

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 (if applicable). Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

Total Health Care Inc. covers a wearable cardioverter defibrillator (e.g., LifeVest™) as medically necessary only as an interim treatment for patients at high risk of sudden cardiac arrest who:

1. Have a left ventricular ejection fraction of 35% or less
2. Have a temporary contraindication to receiving an ICD (such as a systemic infection) at the current time;
3. Are tentatively scheduled for an ICD placement procedure based on one of the following:
a. Received treatment with the goal of an ICD placement and have been scheduled for the ICD placement within three months, or

b. Had an ICD removed and have been rescheduled for placement of another ICD once the contraindication has been treated.

WCDs will be covered as a rental device, with PAs approved for 30 days at a time and a maximum of three months. If there is a continued need for the device beyond 30 days, a new PA request must be submitted documenting all of the following:
1. The beneficiary’s response to and continued need for the WCD,
2. The anticipated date of the ICD procedure, and
3. The beneficiary’s compliance with wearing the WCD. The compliance report from the device showing at least 95% wear compliance must be submitted with the PA request.

Requests for continued PA beyond the maximum of three months will be considered on a case-by-case basis.

Total Health Care covers 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:

1. 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
2. Structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.
3. Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study
4. 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
5. Nonischemic dilated cardiomyopathy (DCM), LVEF less than or equal to 35%, in NYHA functional Class II or III.
6. LV dysfunction due to prior MI, at least 40 days post-MI, LVEF less than 30%, in NYHA functional Class I
7. Nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study
8. Unexplained syncope, significant LV dysfunction, and nonischemic DCM.
9. Sustained VT, with normal or near-normal ventricular function
10. Hypertrophic cardiomyopathy (HCM) with one or more major risk factors for sudden cardiac death (SCD)
11. Arrhythmogenic right ventricular dysplasia cardiomyopathy (ARVD/C), with one or more risk factors for SCD.
12. Long-QT syndrome, experiencing syncope and/or VT while receiving beta blockers
13. Non-hospitalized individuals awaiting transplantation
14. Brugada syndrome with syncope
15. Brugada syndrome with documented VT that has not resulted in cardiac arrest

16. Catecholaminergic polymorphic VT with syncope and/or documented sustained VT while receiving beta blockers
17. Cardiac sarcoidosis, giant cell myocarditis, or Chagas disease
18. Symptomatic sustained VT in a child or adult with congenital heart disease who has undergone hemodynamic and electrophysiological evaluation.
19. 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

Total health care covers an ICD in a child who is receiving optimal medical therapy and has survived cardiac arrest as medically necessary when evaluation fails to identify a reversible cause.

**Exclusions:**

1. Total health care, Inc. does not cover a wearable cardioverter defibrillator (e.g., LifeVest) for any other indication, including but not limited to cardiomyopathy, post coronary artery bypass graft (CABG), or post percutaneous transluminal coronary angioplasty (PTCA), because it is considered experimental, investigational or unproven.

2. Total Health Care, Inc. does not cover WCDs for investigational procedures or patient preference.

3. Total health care, Inc. does not cover an automatic external defibrillator (SEC) 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 for active treatment. An AED in the home is therefore not considered medically necessary.

4. 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:

   a. Need an ICD or already have an operating ICD
   b. Are under age 18
   c. Have a vision or hearing problem that may interfere with reading or hearing the WCD messages
d. Are taking medication that would interfere with pushing the response buttons on the WCD alarm module

e. Are unwilling or unable to wear the device continuously, except when bathing or showering

f. Are pregnant or breastfeeding

g. Are of childbearing age and not attempting to prevent pregnancy

h. 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

Bibliography


http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083949.htm

