Healthy Blue

Medical Policy

Subject:	Wearable Cardioverter Defibrillators		
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Description/Scope

This document addresses the wearable cardioverter defibrillator, an external vest-like garment device that is intended to perform the same tasks as an implantable cardioverter defibrillator (ICD), without requiring any invasive procedures.

For information regarding other technologies for cardiac disease, see:

- CG-SURG-97 Cardioverter Defibrillators
- CG-SURG-63 Cardiac Resynchronization Therapy with or without an Implantable Cardioverter Defibrillator for the Treatment of Heart Failure

Position Statement

Medically Necessary:

The wearable cardioverter defibrillator is considered **medically necessary** for individuals at high-risk of sudden cardiac arrest, who meet the following criteria (A and B):

A. Individuals must meet the medical necessity criteria for an implantable cardioverter defibrillator*; **and**
B. Individuals must have ONE of the following documented medical contraindications to implantation of an implantable cardioverter defibrillator (1, 2, or 3):
   1. Those awaiting a heart transplantation - on waiting list and meet medical necessity criteria for heart transplantation;** **or**
   2. Those with a previously implanted cardioverter defibrillator that requires explantation due to infection (for example, device pocket or lead infection, endocarditis) with waiting period before reimplantation of an implantable cardioverter defibrillator; **or**
   3. Those with an infectious process or other temporary condition (for example, recovery from surgery, lack of vascular access) that precludes immediate implantation of an implantable cardioverter defibrillator.

* Refer to *CG-SURG-97 Cardioverter Defibrillators*
**Refer to *TRANS.00033 Heart Transplantation*

Investigational and Not Medically Necessary:

The wearable cardioverter defibrillator is considered **investigational and not medically necessary** when the criteria listed above are not met.

Rationale

The U.S. Food and Drug Administration (FDA) granted clearance for the Lifecor Wearable Cardioverter Defibrillator (WCD®) 2000 system via premarket application approval in December 2001, based on clinical data submitted to the FDA by the manufacturer, which has subsequently been published in the peer-reviewed literature, and referred to as the BIROAD and WEARIT studies (Feldman, 2004). The trials consisted of prospective, non-randomized studies, which compared the outcomes of the WCD with historical controls of subjects suffering sudden cardiac arrest (SCD) who called 911 emergency services. While this study demonstrated that the WCD could detect arrhythmias and appropriately deliver a counter shock, its long-term efficacy will depend on user compliance, and from a practical perspective, the WCD cannot be continuously worn. For example, the BIROAD and WEARIT studies included 289 subjects; there were 12 deaths reported, and 50% occurred in those who were either not wearing the device or wearing it inappropriately. Additionally, 68 of the 289 subjects discontinued wearing the device due to comfort issues or adverse reactions. Therefore, an implantable cardiac defibrillator (ICD) is considered standard care. A WCD would be considered an alternative to an ICD only in the small subset of individuals that have co-morbidities or other contraindications for an ICD. For example, individuals with an infected ICD requiring removal may benefit from a WCD worn during the limited interim period until an ICD can be reimplanted. Additionally, a small subset awaiting heart transplantation may be considered at high risk for arrhythmia, but are not candidates for an ICD due to co-morbidities. A WCD may be considered an alternative to an ICD in these individuals while they are on the heart transplant waiting list.

Additional prospective data from the Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II) Registry were published in 2015. The WEARIT-II Registry enrolled 2000 subjects with ischemic (n=805, 40%), or nonischemic cardiomyopathy (n=927, 46%), or congenital/inherited heart disease (n=268) prescribed a WCD between August 2011 and February 2014. Clinical data were captured for arrhythmic events, ICD implantation, and improvement in left ventricular ejection fraction (LVEF). The median age was 62 years; the median LVEF was 25%. The median WCD wear time was 90 days with median daily use of 22.5 hours. There was a total of 120 episodes of sustained ventricular tachyarrhythmias in 41 individuals, of whom 54% received appropriate WCD shocks. Only 10 subjects (0.5%) received inappropriate WCD therapy. The rate of sustained ventricular tachyarrhythmias by 3 months was 3% among those individuals with ischemic cardiomyopathy and congenital/inherited heart disease and 1% among subjects with nonischemic disease (p=0.02). At the end of WCD use, 840 subjects (42%) were implanted with an ICD. The most frequent reason not to implant an ICD following WCD use was improvement in LVEF. The authors concluded that the WEARIT-II data demonstrated a high rate of sustained ventricular tachyarrhythmias at 3 months in at-risk individuals who were not eligible for an ICD and suggested that the WCD can be safely used to protect against potentially lethal cardiac events during this period of risk assessment (Kutyifa, 2015). Additional retrospective and database study of WCD use in subgroups of at-risk individuals with newly diagnosed cardiomyopathy (ischemic and nonischemic) were reported with results that indicate a possible role for the WCD in the first few months following a new diagnosis of cardiomyopathy. Further study is needed to inform about this possible use for the WCD (Salehi, 2016; Singh, 2015).

There has been interest in offering WCDs to individuals in the immediate post myocardial infarction (MI) period, when they are considered at high risk of arrhythmia. However, the Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) demonstrated that an ICD is not indicated during this period (Hohnloser, 2004). The DINAMIT trial randomized 674 subjects to receive either an ICD or no ICD within 40 days of an MI. All participants had

reduced ejection fractions (LVEF less than or equal to 35%) and impaired cardiac autonomic function. The primary outcome was death from any cause. The secondary outcome was death from arrhythmia. During a mean follow-up of 30 ± 13 months, there was no difference in overall mortality between the 2 groups. Of 120 subjects who died, 62 were in the ICD group, and 58 were in the control group. There were 12 deaths due to arrhythmia in the ICD group and 29 in the control group. There were 50 deaths from nonarrhythmic causes in the ICD group, however, and 29 in the control group. Nonarrhythmic cardiac causes accounted for 34 of the 50 deaths in the ICD group and 20 of the 29 nonarrhythmic deaths in the control group. The authors concluded that ICD therapy does not reduce overall mortality in high-risk subjects who have recently had an MI. Although ICD therapy was associated with a reduction in arrhythmia-related death, this was offset by an increase in nonarrhythmic-related death. While the nonrandomized BIROAD study investigated subjects treated with a WCD in the immediate post MI period, the results of the large randomized DINAMIT study provide higher grade evidence of the effects of WCD use in this period.

Two prospective, randomized, controlled trials compared the use of ICDs to that of conventional therapy: the Multi-Center Automatic Defibrillator Implantation Trial (MADIT; n=196) and the Multi-Center Automatic Defibrillator Implantation Trial II (MADIT II; n=1232). Both trials were conducted on subjects with coronary artery disease (CAD) who had experienced MIs and who had reduced LVEFs. Both trials were well designed and of good quality. The observed all-cause mortality rate in the conventionally treated group was somewhat lower in MADIT II (19.8%, with average follow-up at 20 months) than in MADIT (38.6%, with average follow-up at 27 months), suggesting some differences in the baseline mortality risk between these 2 populations. Both trials reported that ICD treatment resulted in more statistically significant reductions in all-cause mortality (primary endpoint) than conventional therapy did. The MADIT and MADIT II trials provide consistent evidence that individuals with CAD, prior MI and reduced LVEF who meet selection criteria for either trial have significantly reduced mortality when treated with an ICD (Moss, 1996). However, results of the MADIT II trial concluded that risk of SCD in those with LVEF less than or equal to 30% increases as a function of time from MI. The survival benefit associated with ICD placement appears to be greater for remote MI and remains substantial for up to 15 years after MI (Wilber, 2004).

Additional study of the WCD in the early high-risk period following an acute MI was conducted in the Vest Prevention of Early Sudden Death Trial and the VEST registry data. Both trials were sponsored by the manufacturer (Zoll Medical Corp.) and the University of California at San Francisco with results published in 2018. The VEST study analyzed individuals within 7 days of an MI who had ventricular dysfunction (LVEF ≤ 0.35) to determine if use of the WCD would impact mortality by reducing the incidence of SCD during the first 3 months following acute MI (NCT01446965). There were 1524 participants in the device group and 778 in the control group. The mean LVEF was 28% and 83.6% of participants underwent PCI during the index hospitalization. The primary outcome was the composite of sudden death or death from ventricular tachyarrhythmia at 90 days (arrhythmic death). Secondary outcomes included death from any cause and nonarrhythmic death. There was no significant difference between the 2 groups in the primary outcome of arrhythmic death (1.6% in the device group and 2.4% in the control group; relative risk, 0.67; 95% confidence interval [CI], 0.37 to 1.21; p=0.18). The total mortality was 3.1% in the device group, as compared with 4.9% in the control group (relative risk, 0.64; 95% CI, 0.43 to 0.98; uncorrected p=0.04). The rate of non-arrhythmic death was 1.4% in the device group and 2.2% in the control group (relative risk, 0.63; 95% CI, 0.33 to 1.19; uncorrected p=0.15). Of the 48 participants in the WCD group who died, 12 were wearing the device at the time of death including 9 of the 25 participants who experienced

arrhythmic death. Of these 9 participants who died, 4 had had a ventricular tachyarrhythmia detected and had received appropriate shocks with conversion to sinus rhythm but with subsequent recurrent ventricular tachyarrhythmias or agonal rhythms. In the WCD group, 43 participants (2.8%) never wore the device after randomization; in the control group, 20 participants (2.6%) received the device outside the protocol. The power calculation assumed a device adherence rate of 70%, a goal that was met or exceeded in the first 2 weeks after randomization but that waned over time. A total of 20 participants in the WCD group (1.3%) received an appropriate shock; of these 20 subjects, 14 survived to 90 days indicating that not all successful defibrillations prolong survival. A total of 9 (0.6%) participants in the WCD group received an inappropriate shock. In an as-treated analysis, a significantly lower percentage of participants died when they were wearing the device than when they were not, a finding that remained significant even after the most conservative correction for multiple comparisons. Although this result is subject to bias, it suggests a benefit to wearing the device. The authors concluded that mortality at 90 days was 4.9% in the control group, despite 84% of the participants having undergone PCI for acute MI and more than 85% being treated with GDMT. The WCD did not result in a significantly lower rate of arrhythmic death than medical therapy during the first 90 days post-acute MI. It remains unclear how to reduce the risk of arrhythmic death beyond what is possible with appropriate medical therapy in the early period after MI before ICDs are indicated (Olgin, 2018).

There have been few additional studies of the WCD. Rao evaluated the short- and long-term outcomes of individuals with congenital structural heart disease (CSHD) and those with inherited arrhythmias (IA) who received a WCD for the prevention of SCD. The study population included 162 subjects with CSHD (n=43) and IA (n=119) who were prospectively followed in a nationwide manufacturer-sponsored registry from 2005 to 2010. The mortality rates were compared using Kaplan-Meier survival analysis. It was noted that subjects with CSHD had a greater frequency of left ventricular dysfunction (ejection fraction < 30%) than did those with IA (37% vs. 5%, respectively; p=0.002). The predominant indication for WCD was pending genetic testing in the IA group and transplant listing in the CSHD group. Compliance with the WCD was similar in the two groups (91%). WCD shocks successfully terminated 3 ventricular tachyarrhythmias in the subjects with IA during a median follow-up of 29 days of therapy (corresponding to 23 appropriate WCD shocks per 100 subject-years). No arrhythmias occurred in the subjects with CSHD during a median follow-up of 27 days, and no subjects died while actively wearing the WCD. At 1 year of follow-up, the survival rates were significantly lower among the subjects with CSHD (87%) than among those with IA (97%, p=0.02). The authors concluded that the data suggested the WCD can be safely used in high-risk adult individuals with IA and CSHD, although the subjects with IA showed a greater rate of ventricular tachyarrhythmias during therapy but significantly lower long-term mortality rates (Rao, 2011). Prospective randomized controlled trials are needed to confirm whether the observed results were due to the use of the WCD.

Use of the WCD has been suggested to reduce risk of SCD in pregnancy-associated peripartum cardiomyopathy (PPCM) that typically arises in the peripartum period and is marked by LV dysfunction and heart failure (HF). Thus far, PPCM is not precisely defined, and the timing of this condition is uncertain. The Heart Failure Association of the European Society of Cardiology (HFA/ESC) Study Group on PPCM provided an updated definition of PPCM as, “An idiopathic cardiomyopathy frequently presenting with HF secondary to LV systolic dysfunction (LVEF < 45%) towards the end of pregnancy or in the months following delivery, if no other cause of HF is found” (Bauersachs, 2016). This study group considered the WCD, “An interesting alternative for the prevention of SCD in the first months after diagnosis, until a definitive decision about ICD implantation can be made.” They

recommended early consideration of the WCD in women with LVEF ≤ 35%. The 2018 ESC Guidelines for the Management of Cardiovascular Diseases during Pregnancy provided the same guidance as follows:

> Given the high rate of improvement of LV function during optimal HF drug therapy, early implantation of an ICD in patients with newly diagnosed PPCM or DCM is not appropriate. A WCD may prevent SCD during the first 3–6 months after diagnosis, especially in patients with EF ≤ 35%, allowing protected recovery from severe LV impairment (Regitz-Zagrosek, 2018).

To date, the majority of studies of PPCM incidence have been limited to case series, a single center case control study and population-based study. Preeclampsia, hypertension and multiple gestations predispose to PPCM. The majority of PPCM cases present postpartum, mostly in the week after delivery, but a small subset present during the second and third trimesters. The most common presentation includes signs and symptom of HF. There is very limited data on the prevalence of ventricular arrhythmias in PPCM and effective treatment options. Further study is needed to clarify the risk factors for SCD in PPCM, as well as whether use of the WCD would improve clinical outcomes (Bello, 2013; Duncker, 2014; Saltzberg, 2012).

Background/Overview

The ICD has been proven to be effective in reducing mortality in individuals with episodes of ventricular arrhythmias or in survivors of SCD, often seen in those with CAD. More recently, randomized studies, (that is, the MADIT I and MADIT II trials) have demonstrated that ICDs are effective prophylactic therapy in those who are considered at high risk for lethal arrhythmias, such as those with prior MI and reduced LVEF. ICDs consist of implantable leads in the heart that connect to a pulse generator implanted beneath the skin of the chest or abdomen. In the past, ICD placement required a thoracotomy, but current technology allows implantation with only a minor surgical procedure, with the cardiac leads placed percutaneously. Potential adverse effects of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks.

The WCD is an external device that is intended to perform the same tasks as an ICD, without requiring any invasive procedures. It consists of a vest that is worn continuously underneath the 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 belt. The monitor contains the electronics that interpret the cardiac rhythm and determine when a counter shock is necessary. The alarm module alerts the wearer to certain conditions by lights or voice messages. The U.S. Food and Drug Administration (FDA) gave clearance to the Lifecor WCD® 2000 system via premarket application approval (PMA) in December 2001 for "Adult patients 18 years and older who are at risk for sudden cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The trade name of the WCD 2000 System was changed to LifeVest® in 2002, and the LIFECOR business was acquired by ZOLL Medical Corporation (Philadelphia, PA) in 2006. On December 17, 2015, the FDA expanded its clearance of the LifeVest system to include the following:

> The LifeVest® system is indicated for patients under 18 years of age who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. Patients must have a chest circumference of 26 inches (66 centimeters) or greater and a weight of 18.75 kilograms (41.3 pounds) or greater.

According to the updated FDA label for the LifeVest device, the following is provided within the updated Summary of Safety and Effectiveness data (SSED, 2015):

> The clinical information provided in this submission did not identify any additional safety concerns associated with use of the LifeVest in patients under the age of 18, who are of the appropriate size for the device, than were seen in the complete clinical study for patients over the age of 18 submitted in the Original PMA. Data from the literature cited below has shown the LifeVest's ability to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as thirteen. Four patients in the 3-17 age group and five patients in the 18-21 age group experienced a sudden cardiac arrest during LifeVest use that was successfully converted to a life-sustaining rhythm. While a successful shock was not reported in a patient younger than 13, the AHA dosing guidelines for external defibrillation suggest that we can expect an appropriate shock to be effective in any patient who meets the weight requirement stated in the Indications for Use.

There are three peer-reviewed articles on the use of the LifeVest specifically in the pediatric population, which were described in the literature as follows:

> One recent paper describes 4 pediatric individuals prescribed a WCD from a single site (Everitt, 2010). All carried a diagnosis of anthracycline-induced cardiomyopathy. None of these individuals had an appropriate or inappropriate shock. Two trial participants had documented noncompliance with wear, which resulted in failure to detect and treat a life-threatening arrhythmia in one. While no trial subjects received an appropriate treatment in this study, none received an inappropriate treatment despite the inappropriately detected rhythm caused by ECG noise. The paper concluded that the WCD is a short-term alternative for children at risk for SCD, who can be properly fit with the WCD, where the risk of ICD use is greater than the benefit.
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> In a paper by Collins (2010), 81 multi-site WCD individuals from 9-18 years old, and 103 subjects aged 19-21, were retrospectively reviewed. In subjects aged 19-21 years, there were five appropriate treatments in 2 subjects and one inappropriate treatment in a single subject. In subjects ≤ 18 years of age, there was one inappropriate therapy, due to sinus tachycardia and artifact, and one withholding of therapy, due to a device-device interaction. Compliance was generally similar to adults among these younger individuals, with an average daily use of 19 hours, and non-compliance or comfort issues only being recorded for 7-11% of trial participants. This paper concluded that the WCD could be an appropriate therapy for pediatric individuals who are at risk for SCD, as they had two appropriate treatments in their young adult population (age 19-21). However, they had no appropriate treatments in their pediatric population (age 9-18).
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> The third paper by LaPage (2008) detailed the fatal device-device interaction between the WCD and a unipolar epicardial pacemaker. Such interactions are not unique to pediatric individuals nor are they unique to wearable defibrillators, being extensively described in the ICD and AED literature. LifeVest manuals have included specific warnings about pacemaker interactions since the initial FDA approval. These warnings advise physicians to use appropriate caution when

> prescribing the LifeVest device to an individual who is dependent on a pacemaker. There was only one serious adverse event reported in the literature for pediatric subjects using the LifeVest.

The updated FDA premarket approval required that a post-approval study be performed as follows:

> The study will consist of a serial, prospective data collection of patients under 18 years of age utilizing the LifeVest WCD who meet the proposed indication for the treatment of life-threatening arrhythmias. The data will be collected via medical order database, device generated records, and customer call reports for each device use. Patient demographics collected will include age, gender, and ICD-9 code(s) describing the patient's condition. Performance information will include daily compliance with use, duration of use, appropriate therapy delivery, ECG recordings during appropriate therapy delivery, and any available description of the circumstances found within the Call Report Database. Safety data to be included are inappropriate defibrillation therapy delivery, ECG recordings during inappropriate therapy delivery and any available description of the circumstances found within the Call Report Database, and adverse events reported to ZOLL through the customer support or technical support departments. The data on the first 150 patients who meet the proposed indication will be collected and data will be obtained from the returned device (P010030/S056).

This study is the Vest Trial and VEST registry which is listed as completed; only one article has been published about the results, which has been detailed earlier in this document (Olgin, 2018).

On July 27, 2021, the ASSURE® Wearable Cardioverter Defibrillator (A-WCD) System (Kestra Medical Technologies, Inc. Kirkland, WA) received FDA PMA approval. The ASSURE system is a non-invasive, external, individually worn device which is designed to automatically evaluate an electrocardiogram (ECG) for life-threatening ventricular arrhythmias and deliver a shock (defibrillation) to the heart to restore an effective rhythm. The approval order statement states that the ASSURE System "Is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator." The ASSURE system is contraindicated for use in individuals with an active ICD. FDA clearance was based on results of the ASSURE WCD Clinical Evaluation – Detection and Safety Study (ACE-DETECT, NCT 03887052), which was a multicenter prospective, nonrandomized trial that evaluated the ASSURE WCD (A-WCD) for false alarm rates, wear compliance, and adverse events (AEs) in ambulatory subjects. Trial participants included subjects (n=130) who had an LVEF ≤ 40% and an active ICD. Detection was enabled in the A-WCD group and shock alarm markers were recorded, but shocks and shock alarms were disabled. All WCD episodes and ICD detected VT/VF episodes were adjudicated. The primary outcome measured the false positive shock alarm rate with a performance goal of one every 3.4 days (0.29 per patient-day). Additional outcomes included a summary of A-WCD and ICD detected episodes and individually self-reported outcomes including perceived comfort, adverse events determined to be possibly related to use of the A-WCD and wear compliance. Trial participants were followed for 30 days with clinical follow-up weekly by phone, and they returned for final follow-up at the end of the 30-day participation period. No ICD recorded VT/VF episodes meeting WCD detection criteria (≥ 170 bpm for ≥ 20 s) were missed by the A-WCD group during 3501 subject-days of use. The median wear was 31.0 days. Adverse events were mostly mild (skin irritation [19.4%] and musculoskeletal discomfort [8.5%]). Limitations noted by the authors included the small sample size and short-term follow-up which limited the generalizability of the results. Further, since the

auditory/vibratory alarms and shocks were disabled, the reported wear compliance may not reflect clinical use when this functionality is enabled. The study concluded that the ASSURE WCD demonstrated a low false-positive shock alarm rate, low self-reported discomfort and no serious adverse events (Poole, 2022).

The FDA approval also requires an Annual Report that must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device. As part of the annual report, the number of devices returned to the applicant for normal end-of-life and alleged failures or malfunctions must be provided. A summary of information should be provided that includes defibrillation success and the number of shocks required for success, identification of any error codes or malfunctions during use and their related MDR number. Lastly, a listing of any safety alerts, technical service bulletins, user communications, or recalls for devices should be included (FDA, 2021).

In addition to the Annual Report requirements, the following data is also required in post-approval study (PAS) reports:

> The ASSURE WCD Clinical Evaluation (ACE-PAS), will be conducted. The study will consist of active surveillance using real-world data collected in the ASSURE Registry. A total of 271 appropriate shock episodes for VT/VF is required to provide the required level of statistical precision for the primary effectiveness outcome. It is estimated that a total of 5,179 patients will be required to provide data on 271 appropriate shock episodes. The device will be used temporarily (days of use), and the data will be obtained from that period of use. No additional patient follow-up is required.
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> The primary safety outcome measures the inappropriate shocks per patient-month of use (total inappropriate shocks/cumulative months of device use for all patients) ≤ 0.0075. The FDA requires the first report be provided after 500 patients. Following the initial report, subsequent reports will be provided every six months until the required sample size is achieved, and a final report is generated. PAS Progress Reports must be submitted every six months until subject enrollment has been completed, and annually thereafter. If milestones are not met, quarterly enrollment status reports (i.e., every 3 months) must be submitted in addition to periodic (6-months) PAS Progress Reports, until FDA states otherwise (FDA, 2021).

Definitions

Cardiac arrhythmia: A disturbance in the electrical activity of the heart that manifests as an abnormality in the heart rate or heart rhythm. Individuals with arrhythmias may experience a wide variety of symptoms ranging from palpitations to fainting.

Coronary artery: A pair of vessels that supply blood to the myocardium (middle layer of the walls of the heart).

Coronary artery disease (CAD): This condition involves narrowing of the coronary arteries that is sufficient enough to prevent adequate blood supply to the myocardium.

Defibrillation: A treatment in which an electronic device sends an electric shock to the heart to stop an extremely rapid, irregular heartbeat, in order to restore the normal heart rhythm.

Ejection fraction (also referred to as left ventricular ejection fraction [LVEF]): A measure of ventricular contractility.

Electrophysiologic study (EPS) of the heart: This is a test of the electrical conduction system of the heart (the system that generates the heartbeat).

Fibrillation: This term refers to very rapid contractions or twitching of small muscle fibers in the heart.

Tachycardia: An abnormally rapid heartbeat.

Ventricle: One of two lower chambers of the heart.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services may be Medically Necessary when criteria are met:

CPT

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

HCPCS

K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/11/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. The Background and References sections were updated.
	11/22/2021	Added cross-references with hyperlinks for CG-SURG-97 and CG-SURG-63.
Revised	08/12/2021	MPTAC review. The INV/NMN statement has been revised for clarification to say the WCD is considered INV/NMN when the criteria are not met. The Rationale and References sections were updated.
Reviewed	08/13/2020	MPTAC review. References were updated.
Reviewed	08/22/2019	MPTAC review. The Rationale and References sections were updated.
Reviewed	11/08/2018	MPTAC review. The Rationale and References sections were updated.
Revised	07/26/2018	MPTAC review. The document header wording was updated from "Current Effective Date" to "Publish Date." The acronyms (WCD, ICD, others) were removed from the Position Statements. The Rationale and References sections were updated.
Reviewed	08/03/2017	MPTAC review. References were updated.
Revised	08/15/2016	MPTAC review. Interim MPTAC review approved the addition of newly diagnosed NIDCM during the initial treatment period of 3 months of GDMT to the investigational and not medically necessary indications for the WCD.
Revised	08/04/2016	MPTAC review. Updated the formatting in the Position Statement section. Examples were added to Criterion No. B2 and B3. The Rationale, Background and References were updated. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. References were updated.
Reviewed	08/14/2014	MPTAC review. References were updated.
Reviewed	11/14/2013	MPTAC review. References were updated.
Reviewed	11/08/2012	MPTAC review. References were updated. Updated Coding section to include 01/01/2013 CPT descriptor change.
Reviewed	11/17/2011	MPTAC review. The Rationale and References were updated.
Reviewed	11/18/2010	MPTAC review. References and Coding were updated.
Reviewed	11/19/2009	MPTAC review. References were updated.
Reviewed	11/20/2008	MPTAC review. Consideration was given to expansion of medically necessary indications/criteria to add the immediate post-acute MI recovery period (first 40 days) in response to specialty society recommendation but no revision to existing criteria was approved by MPTAC. Annual Review research was also performed. The Rationale and Reference sections were updated. Updated Coding section with 01/01/2009 CPT changes.

Revised	11/29/2007	MPTAC review. The criteria considered investigational and not medically necessary regarding: "History of an acute myocardial infarction within thirty days" has been revised from 30 to 40 days post-MI for consistency with SURG.00033 (ICD criteria regarding no history of MI in the last *forty* days). Also, the phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." References were also updated.
Reviewed	12/07/2006	MPTAC review. References and coding were updated.
Revised	12/01/2005	MPTAC revised. Added additional indication for WCD i.e., patients with an infectious process or other temporary condition that precludes initial implantation of an ICD.
Revised	09/22/2005	MPTAC review. Position Statement: Provided clarification that candidates must have a documented medical contraindication to ICD placement with either of the following: those awaiting a heart transplantation - on waiting list and meets medical necessity criteria for heart transplantation, **or** those with a previously implanted ICD that requires explantation due to infection with waiting period before ICD reinsertion.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	07/28/2005	MED.00049	Automatic External Defibrillators and Wearable Cardioverter Defibrillators
WellPoint, Inc.	04/28/2005	9.04.04	Wearable Cardioverter Defibrillators for Prevention of Sudden Cardiac Death