Cigna Medical Coverage Policy

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

Effective Date **2/15/2014**
Next Review Date **1/15/2015**
Coverage Policy Number **0431**

Table of Contents

Hyperlink to Related Coverage Policies

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

INSTRUCTIONS FOR USE
*The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, 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 customer'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 customer's benefit plan document **always supersedes** 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 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. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 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 ANY 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) for EITHER of the following:
  - history of ventricular tachycardia or ventricular fibrillation after the first 48 hours
  - left ventricular ejection fraction (LVEF) $\leq$ 35%

- For primary prevention, as a bridge to ICD risk stratification and possible implantation for newly diagnosed dilated cardiomyopathy (ischemic or nonischemic) with LVEF $\leq$ 35%

Cigna does not cover a wearable cardioverter defibrillator (e.g., LifeVest) for any other indication, because it is considered experimental, investigational or unproven.

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):**

Secondary Prevention

Cigna covers an implantable cardioverter defibrillator (ICD) as medically necessary for ANY of the following indications:

- **Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (< 48 hours) myocardial infarction (MI) (newly diagnosed, no recent prior assessment of left ventricular ejection fraction (LVEF), and ANY of the following:**
    - Revascularization completed after cardiac arrest, and EITHER of the following:
        - Recurrent VF or polymorphic VT during/following acute (< 48 hours) MI
        - VF or polymorphic VT during/following acute MI, nonsustained ventricular tachycardia (NSVT) 4 days post MI, Inducible VT/VF at electrophysiologic study (EPS) ≥ 4 days after revascularization
    - No revascularization needed (i.e., no significant CAD), but recurrent VF or polymorphic VT during/following acute MI
    - Obstructive CAD with coronary anatomy not amenable to revascularization,with VF or polymorphic VT during/following acute MI
- **CAD: VF or hemodynamically unstable VT <48 hours post-elective revascularization, with no evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause)**
- **CAD: VF or hemodynamically unstable VT (no recent MI [within the past 40 days] prior to VF/VT and/or no recent revascularization [3 Months] prior to VF/VT) and ANY of the following:**
    - No identifiable transient and completely reversible causes, and no need for revascularization identified by catheterization performed following VF/VT
    - Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization
    - Significant CAD identified at catheterization performed following VF/VT, and revascularization performed after cardiac arrest
- **CAD: VF or hemodynamically unstable VT during exercise testing associated with significant CAD and ANY of the following:**
    - Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization)
    - Significant CAD identified at catheterization performed following VF/VT, and revascularization performed after cardiac arrest.
- **No CAD, VF or Hemodynamically Unstable VT and ANY of the following:**

- Dilated nonischemic cardiomyopathy
- VT/VF associated with cocaine abuse, LVEF≤ 35%
- Severe valvular disease, VT/VF < 48 hours after surgical repair or replacement of aortic or mitral valve, with no evidence of postoperative valvular dysfunction
- VF/hemodynamically unstable VT associated with ANY of the following:
    - Myocardial sarcoidosis
    - Myocarditis or giant cell myocarditis
    - Takotsubo cardiomyopathy (stress-induced cardiomyopathy, apical ballooning syndrome) ≥ 48 hours of onset of symptoms

- **Genetic conditions associated with sustained VT, VF (i.e., congenital long QT, short QT, catecholaminergic polymorphic VT, Brugada syndrome, arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy)**

- **Absence of structural heart disease (LVEF >50%) or known genetic causes of sustained VT/VF, and EITHER of the following:**

    - Idiopathic VF with normal ventricular function
    - Bradycardia dependent VT/VF

- **Unexplained syncope in the absence of structural heart disease in an individual with long QT syndrome, Brugada ECG pattern, catecholaminergic polymorphic VT**

- **Unexplained syncope in an individual with prior MI and no acute MI, with LVEF 36%-49% and ANY of the following:**

    - Nonobstructive CAD, revascularization is not indicated, and EPS failed to define a cause of syncope
    - Obstructive CAD not amenable to revascularization, and EPS failed to define a cause of syncope
    - EPS revealed inducible sustained VT/VF

- **Unexplained syncope in an individual with prior MI and no acute MI. LVEF ≤ 35%**

- **Unexplained syncope in an individual with left ventricular hypertrophy/hypertensive heart disease, LVEF ≤ 49%**

- **Unexplained syncope in individual with nonischemic cardiomyopathy and ANY of the following:**

    - Nonischemic dilated cardiomyopathy, LVEF ≤ 49%
    - Left ventricular non-compaction
    - Hypertrophic cardiomyopathy
    - Cardiac amyloidosis
    - Tetralogy of Fallot with prior corrective surgery

- **Unexplained syncope in individual with arrhythmogenic right ventricular cardiomyopathy**

- **Sustained hemodynamically stable monomorphic VT associated with structural heart disease and ANY of the following:**

    - CAD and prior MI
    - Nonischemic dilated cardiomyopathy
    - Bundle branch re-entry successfully ablated in individual with nonischemic cardiomyopathy. LVEF ≤ 49%
    - Bundle branch re-entry successfully ablated in individual with nonischemic cardiomyopathy. LVEF ≤ 49%

Primary Prevention

Cigna covers an implantable cardioverter defibrillator (ICD) as medically necessary for ANY of the following indications:

- **Post-acute Myocardial Infarction (MI) (≤ 40 days) and revascularization, with LVEF ≤ 30% and BOTH of the following:**
  - Asymptomatic nonsustained ventricular tachycardia (NSVT) (>4 days post MI).
  - EPS with inducible sustained VT (EPS performed after revascularization, within 40 days after MI
- **Post-acute MI (< 40 days), with obstructive CAD, not revascularized, with coronary anatomy not amenable to revascularization, and BOTH of the following:**
  - Asymptomatic NSVT (>4 days post MI)
  - EPS with inducible sustained VT (EPS performed within 40 days after MI
- **Post acute MI (≤ 40 days) and revascularization, with LVEF 31%-40% and BOTH of the following:**
  - Asymptomatic NSVT (>4 days post MI)
  - EPS with inducible sustained VT (EPS performed after revascularization, within 40 days after MI)
- **Post acute MI (≤ 40 days) with pre-existing chronic cardiomyopathy (≥ 3 Months) and ANY of the following:**
  - LVEF < 30% due to old infarction. New York Heart Association (NYHA) class I
  - LVEF < 35% due to old infarction. NYHA class II=III
  - LVEF < 35% due to nonischemic causes. NYHA class II-III
- **Post-MI (≤ 40 Days) and need for guideline-directed pacemaker therapy post-MI (e.g., sick sinus syndrome (SSS), complete heart block (CHB), or other indications for permanent pacemaker**),, with **LVEF ≤ 40%**
- **Post-MI (>40 Days) with ischemic cardiomyopathy, no recent percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) and EITHER of the following:**
  - LVEF ≤ 35%
  - LVEF 36%-40%. asymptomatic NSVT
- **Post-MI (>40 Days) with ischemic cardiomyopathy, with recent PCI or CABG (≤ 3 months, and ANY of the following:**
  - No known pre-existing cardiomyopathy, LVEF ≤ 35
  - Pre-existing documented cardiomyopathy. LVEF ≤ 35% on guideline-directed medical therapy > 3 months before PCI/CABG
  - LVEF ≤ 40%, with need for permanent pacemaker post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker)
- **Ischemic cardiomyopathy without recent MI (revascularization not indicated), with LVEF ≤ 35%, on guideline-directed medical therapy**
- **Nonischemic cardiomyopathy, at least 3 months on guideline-directed medical therapy, with LVEF ≤ 35%, NYHA Class I-III**
- **Individual with ANY of the following conditions:**

- Sarcoid heart disease,
- myotonic dystrophy
- Chagas disease
- Amyloidosis with heart failure
- Acute lymphocytic myocarditis, newly diagnosed (< 3 months)
- Giant cell myocarditis
- Peripartum cardiomyopathy, persists > 3 months postpartum, LVEF ≤ 35%

- **Individual with ANY of the following genetic conditions (excludes syncope and sustained VT, addressed above)**

    - Hypertrophic cardiomyopathy with 1 or more risk factors
    - Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia
    - Congenital long QT Syndrome with 1 or more risk factors
    - Catecholaminergic polymorphic VT with nonsustained VT (without syncope)
    - Incidentally discovered Brugada by ECG (type I ECG pattern) in the absence of symptoms or family history of sudden cardiac death, with inducible VT or VF at EPS
    - Familial dilated nonischemic cardiomyopathy (RV/LV) associated with sudden cardiac death, and ANY of the following:
        - Evidence of structural cardiac disease, but LVEF > 35%
        - Normal ECG and echo, but carrying the implicated gene
        - LV non-compaction with LVEF > 35%

Cigna 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.

Cigna covers an ICD in a child with hypertrophic cardiomyopathy and unexplained syncope, massive left ventricular hypertrophy, or family history of sudden cardiac death as medically necessary.

Cigna does not cover an ICD for any other indication because it is considered experimental, investigational or unproven.

Cigna covers replacement of an ICD pulse generator and/or leads as medically necessary.

Cigna does not cover an entirely subcutaneous implantable cardioverter defibrillator system (CPT codes 0319T, 0320T, 0321T, 0323T, 0325T, 0326T, 0327T, 0328T) for any indication because it is considered experimental, investigational or unproven.

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 has been proposed as an option for patients who are at risk for sudden cardiac arrest and who are not candidates for or refuse an ICD. The device has also been proposed as a bridge to ICD risk stratification and possible implantation for high-risk patients following acute myocardial infarction (MI), patients diagnosed with cardiomyopathy, and those who have undergone coronary artery bypass graft (CABG) surgery or percutaneous coronary angioplasty (PTCA).

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.

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 with low complication rates. 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 ≤ 35%. In addition, the WCD may be reasonable as a bridge to ICD risk stratification in patients with newly diagnosed ischemic or nonischemic dilated cardiomyopathy. A percentage of such patients may demonstrate an improvement in LVEF after a period of guideline-directed medical therapy to a degree that an ICD is not required.

A rental period of up to three months is reasonable for an individual with newly diagnosed dilated cardiomyopathy, and for a period of up to 40 days immediately following MI, when used as a bridge to ICD risk stratification (as described above), An initial rental period of up to two months is indicated for patients who are awaiting ICD reimplantation and those with a systemic infection or temporary condition that precludes implantation, For patients awaiting cardiac transplantation, an initial rental period of three months is generally indicated, with continued coverage for ongoing rental until transplantation, provided that it is determined upon review that the patient is fully compliant with use of the device.

Literature Review

The prospective nonrandomized multicenter trial submitted as part of the FDA PMA for the WCD 2000 System was published in 2004 (Feldman, et al., for the WEARIT/BIROAD Investigators). 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. **4**

A California Technology Assessment Forum (CTAF) technology assessment, 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).

Chung et al. (2010) published aggregate experience with the LifeVest from 2002 to 2006, with data obtained from the manufacturer's database. The mean duration of use was 52.6 ± 69.6 days, and mean daily use was 19.9 ± 4.7 hours. Of 2169 patients with recorded data, 307 (14.2%) stopped wearing the WCD prematurely due to comfort issues or adverse reactions (primarily the size and weight of the monitor). Eighty sustained ventricular tachycardia (VT)/ventricular fibrillation (VF) events occurred in 59 patients (1.7%), and the first shock was successful in 79 of 80 patients. Eight patients died after successful conversion of unconscious VT/VF. Four patients died due to recurrent arrhythmias after initially recovering consciousness. Not all cardiac arrests were secondary to arrhythmias; asystole occurred in 23 patients resulting in 17 deaths; and three additional patients died due to pulseless electrical activity (2) and respiratory arrest (1), representing 24.5% of cardiac arrests..

The risk of sudden death following acute myocardial infarction (MI) is highest early after the event, and declines progressively over the next six to twelve months. Following an acute MI, the estimate of left ventricular ejection is not reliable and may improve during the subsequent weeks. According to current guidelines and standard practice, a decision regarding ICD implantation should be deferred for at least a month to allow accurate estimation of LVEF and reliable determination of whether an ICD is indicated. The WCD has been proposed as a bridge to ICD risk stratification and possible implantation.

A Blue Cross Blue Shield Technology Evaluation Center (TEC) Assessment, Wearable Cardioverter Defibrillator as a Bridge to Implantable Cardioverter-Defibrillator Treatment was published in 2010. Five studies met the inclusion criteria; two uncontrolled studies that evaluated the ability of the WCD to detect and abort ventricular arrhythmias, and three randomized controlled trials of early ICD implantation for patients at high risk for ventricular arrhythmias. The uncontrolled studies included the WEARIT/BIROAD study discussed above, and a small study by Auricchio et al. (1998) (n=15) that evaluated the WCD in the electrophysiology lab. During the procedure to implant an ICD, or as part of routine testing of an ICD, patents wore the WCD while ventricular arrhythmias were induced. The WCD detected and successfully terminated induced ventricular arrhythmias in 9 of 10 cases. Two of the randomized controlled trials evaluated ICD use in the early post-MI period (Hohnloser et al., 2004; Steinbeck et al., 2009) and the third evaluated ICD use in patients following coronary artery bypass graft (CABG) surgery Bigger, 1997). The DINAMIT study (Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) by Hohnloser et al. followed 674 patients 6–40 days following an MI and found no difference in total mortality between patients who received an ICD and the control group. The trial by Steinbeck et al., Immediate Risk Stratification Improves Survival (IRIS), was similar to the DINAMIT trial in design and in results. The ICD group had a decreased rate of sudden cardiac death that was offset by a higher rate of non-sudden cardiac death. The Bigger trial evaluated ICD use in high-risk post-CABG patients, and found no difference in overall mortality between patients treated with an ICD compared to the control group.

Evidence published to date from several randomized controlled trials has failed to show a survival benefit for ICD implantation early after MI. The reasons for this acute MI-sudden cardiac death paradox are not yet clear. The pathophysiology of sudden cardiac death in the early post-MI period may differ from that which occurs in the later post-MI period. Since sudden cardiac death is not synonymous with an arrhythmic event, it is possible that the increased incidence of sudden death after acute MI is largely not caused by a lethal ventricular arrhythmia. Neither an ICD nor a WCD, therefore, would be expected to have an impact on this type of sudden death. In addition, high-voltage ICD shocks have been associated with several deleterious effects, including transient myocardial dysfunction and troponin release/elevation, and whether these effects occur more frequently in the setting of a healing vs. healed MI requires further study (Goldberger and Passman, 2009).

Rao et al. (2011) conducted an analysis of registry data to evaluate the short-and long-term outcomes of patients with congenital structural heart disease (CSHD) (n=43) and inherited arrhythmias (IA) (n=119) at risk for ventricular tachyarrhythmias and sudden cardiac death who received a wearable cardioverter defibrillator (WCD). The most frequent indication for WCD was pending genetic testing in the IA group and transplant listing in the CSHD group. Compliance was 91% in both groups. Three ventricular tachyarrhythmias were successfully terminated in IA patients during a median follow-up of 29 days of therapy. No arrhythmias occurred in the patients with CSHD during a median follow-up of 27 days. No patients died while actively wearing the WCD.

A retrospective review by Saltzberg et al. (2012) evaluated characteristics and outcomes of peripartum vs. non-peripartum cardiomyopathy in women using a WCD. WCD medical orders from 2003 to 2009 and death index searches were used to identify women with peripartum cardiomyopathy (PPCM) (n=107) and matched non-pregnant women with nonischemic dilated cardiomyopathy (NIDCM) (n=159). WCD use averaged 124 ± 123

days for PPCM patients and 96 ± 83 days among NIDCM patients. No PPCM patients received an appropriate shock for ventricular tachycardia/ventricular fibrillation. Twenty-eight PPCM patients (26%) had improvement in EF from baseline to ≥35%, and WCD use was discontinued, while 21 patients (20%) were implanted with an ICD due to persistent ventricular dysfunction. In the NIDCM group, one patient with an ejection fraction of 15%, New York Heart Association Class IV Heart Failure, received two successful shocks and subsequently received an ICD. Twenty patients (13%) discontinued WCD use due to improvement in EF, and 64 (40%) underwent ICD implantation due to persistent ventricular dysfunction. Fourteen (9%) patients ended WCD use early due to non-adherence, discomfort or skin irritation. Eleven of the NIDCM patients died during WCD usage; seven deaths were reported as cardiac related, and the cause was unknown in the remaining four patients. Ten of the eleven patients who died were not wearing the device at the time of death; details on the 11th patient were not available. Thirteen patients in the NIDCM group died after WCD usage at an average of 10.9 (± 7.8 months) after use), while 3 patients in the NIDCM group died after WCD use; one at 30 months, one at 40 months, and one was lost to follow-up. Adherence was an issue with both groups; the WCD was only worn an average of 17 to 18 hours per day (median 19-20) The authors noted that the implications are compelling, since sudden cardiac death is an unpredictable event, and these women were unprotected 25-30% of each day. The fact that the WCD can be removed by the user compromises overall compliance and effectiveness.

Epstein et al (2013) published observational data from the manufacturer's database of WCD use in patients considered to be at high risk for sudden cardiac arrest following acute MI. Between September 2008 and July 2011, a WCD was prescribed for 8.678 patients post-MI who met the study criteria, i.e. coded as having had a recent MI with ejection fraction ≤ 35%, or given an ICD-9 diagnosis of acute MI. Of these patients, 225 were not fitted with the device or did not wear it for various reasons, leaving 8,453 patients. A total of 133 patients (1.6%) received 309 appropriate shocks during 146 shock events, 252 successfully terminated VT/VF, 9 led to asystole, 41 were unsuccessful, one resulted in nonsustained VT, one resulted in supraventricular tachycardia, and in five patients rhythm outcomes were unknown. The survival rate per patient of those who received appropriate shocks was 91%; of these initial survivors, three died within two days, and 41 died ≥ three days after shock delivery. Actuarial survival analysis of patients treated with appropriate shocks demonstrated cumulative survival at 3, 6, and 12 months of 73%, 70%, and 65%, respectively. Thirty four additional deaths occurred while wearing the device due to bradycardia or asystole events not associated with VT/VF. There were 114 inappropriate shocks in 99 patients.

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 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction (O'Gara et al.) does not include a recommendation for WCD use. In a background discussion of assessment of risks of sudden cardiac death, the authors state that the utility of a wearable cardioverter-defibrillator in high-risk patients during the first 4 to 6 weeks after STEMI is under investigation.

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, nor does a 2012 focused update of this guideline (Tracy et al.)

Use of a wearable cardioverter defibrillator is not mentioned in American College of Cardiology Foundation (ACCF), Heart Rhythm Society (HRS), American Heart Association (AHA), American Society of Echocardiography (ASE), Heart Failure Society of America (HFSA), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Cardiovascular Computed Tomography (SCCT), and Society for Cardiovascular Magnetic Resonance (SCMR) 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy.
Level of evidence: 5

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 of 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 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.

Use Outside the U.S.
As stated above, ACC, AHA and European Society of Cardiology (ESC) 2006 Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death) states that a WCD has been approved by the FDA, but use of a WCD is not included in the guideline recommendations.

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 an individual with newly diagnosed dilated cardiomyopathy and left ventricular ejection fraction of ≤ 35%, or for an individual in the immediate post-MI period with either 1.) a history of ventricular tachycardia or ventricular fibrillation at least 48 hours after the acute MI, or 2.) a left ventricular ejection fraction ≤ 35%. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of the WCD for any other indication.

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: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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

Not Medically Necessary/Not Covered:

HCPCS Codes	Description
E0617	External defibrillator, with integrated electrocardiogram analysis

ICD-9-CM Diagnosis Codes	Description
	All codes

References

1. Antman EM, Anber DT, Armstrong, PW, Bates ER, Green LA, Hand M, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction; A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of patients with acute myocardial infarction). J Am Coll Cardiol. 2004 Aug 4;44(3):E1-E211.

2. Auricchio A, Klein H, Geller CJ, Reek S, Heilman MS, Szymkiewicz SJ. Clinical efficacy of the wearable cardioverter-defibrillator in acutely terminating episodes of ventricular fibrillation. Am J Cardiol. 1998 May;81(10):1253-6.

3. Bardy GH, Lee KL, Mark DB, Poole JE, Toff WD, Tonkin AM, et al., for the HAT Investigators. Home use of automated external defibrillators for sudden cardiac arrest. N Engl J Med. 2008 Apr 24;358(17):1793-804. Epub 2008 Apr 1

4. BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Wearable Cardioverter-Defibrillator as a Bridge to Implantable Cardioverter-Defibrillator Treatment. TEC Assessment Program. Vol. 25, No. 2. Chicago IL: BCBSA; 2010 Nov. Executive Summary. Accessed Dec 13, 2013. Available at URL address: http://www.bcbs.com/blueresources/tec/press/wearable-1.html

5. Chung MK, Szymkiewicz SJ, Shao M, Zishiri E, Niebauer MJ, Lindsay BD, Tchou PJ. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. J Am Coll Cardiol. 2010 Jul 13;56(3):194-203

6. ECC Committee, Subcommittees and Task Forces of the American Heart Association. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2005 Dec 13;112(24 Suppl):IV1-203. Epub 2005 Nov 28.

7. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institue, 2013 May. LifeVest Wearable Defibrillator (Zoll Medical Corp.) for Detection and Treatment of Ventricular Arrhythmia. Available at URL address; http://www.ecri.org

8. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS,et al. American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices); American Association for Thoracic Surgery; Society of Thoracic Surgeons. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Am Coll Cardiol. 2008 May 27;51(21):e1-62.

9. Feldman AM, Klein H, Tchou P, Murali S, Hall WJ, Mancini D, et al. Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD. Pacing & Clinical Electrophysiology. 2004 Jan;27(1):4-9.

10. Feldman MD. Wearable cardioverter defibrillator for patients at risk for sudden cardiac arrest. San Francisco, CA: California Technology Assessment Forum (CTAF). 2009 Mar 11. Accessed Dec 16, 2013. Available at URL address: http://www.ctaf.org/assessments/wearable-cardioverter-defibrillator-patients-risk-sudden-cardiac-arrest

11. Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky, et al. ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices--summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). J Am Coll Cardiol. 2002 Nov 6;40(9):1703-19.

12. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, BcBurnie MA: Public Access Defibrillation Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med. 2004 Aug 12;351(7):637-46.

13. Hazinski MF, Idris AH, Kerber RE, Epstein A, Atkins D, Tang W, Lurie K. Lay rescuer automated external defibrillator ("public access defibrillation") programs: lessons learned from an international multicenter trial: advisory statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. Circulation. 2005 Jun 21;111(24):3336-40.

14. Hunt SA. Hunt SA; American College of Cardiology; American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure).J Am Coll Cardiol. 2005 Sep 20;46(6):e1-82. Erratum in: J Am Coll Cardiol. 2006 Apr 7;47(7):1503-1505.

15. Klein HU, Meltendorf U, Reek S, Smid J, Kuss S, Cygankiewicz I, et al. Pacing Clin Electrophysiol. 2009 Nov 2. [Epub ahead of print].

16. Lee BK, Olgin JE. Role of wearable and automatic external defibrillators in impriving survival in patients at risk for sudden cardiac death. Curr Treat Options Cardiovasc Med. 2009 Oct;11(5):360-5.

17. Marenco JP, Wang PJ, Link MS. Improving survival from sudden cardiac arrest: the role of the automatic external defibrillator. JAMA. 2001 Jul;286(1):47-9.

18. Mitrani RD, McArdle A, Slane M, Cogan J, Myerburg RJ. Wearable defibrillators in uninsured patients with newly diagnosed cardiomyopathy or recent revascularization in a community medical center. Am Heart J. 2013 Mar;165(3):386-92. doi: 10.1016/j.ahj.2012.12.014. Epub 2013 Jan 22.

19. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv. 2013 Jul 1;82(1):E1-27. doi: 10.1002/ccd.24776. Epub 2013 Jan 8.

20. Pelosi F, Morady F. Sudden cardiac death and implantable cardioverter-defibrillators. In: Topol EJ, editor. Textbook of cardiovascular medicine, 3rd ed. Lippincott, Williams & Wilkins; 2007.

21. Pouleur AC, Barkoudah E, Uno H, Skali H, Finn PV, Zelenkofske SL, et al.; VALIANT Investigators. Pathogenesis of sudden unexpected death in a clinical trial of patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. Circulation 2010 Aug 10;122(6):597-602. Epub 2010 Jul 26.

22. Rao M, Goldenberg I, Moss AJ, Klein H, Huang DT, Bianco NR, et al. Wearable defibrillator in congenital structural heart disease and inherited arrhythmias. Am J Cardiol. 2011 Dec 1;108(11):1632-8. Epub 2011 Sep 3.

23. Saltzberg MT, Szymkiewick S, Bianco NR. Characteristics and outcomes of peripartum versus nonperipartum cardiomyopathy in women using a wearable cardiac defibrillator. J Card Fail. 2012 Jan;18(1):21-7. Epub 2011 Oct 19.

24. Solomon Sd, Zelenkofske S, McMurray JJV, Finn PV, Velasquez E, Ertl G, Harsanyi A, et al. Sudden death in patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. N Engl J Med. 2005 Jun 23;352(25):2581-8. Erratum in: N Engl J Med. 2005 Aug 18;353(7):744.

25. Swerdlow CD, Hayes DL, Zipes DP. Pacemakers and Implantable Cardioverter Defibrillators. In: Bonow: Braunwald's heart disease, a textbook of cardiovascular medicine. Saunders, and imprint of Elsevier; 2011.

26. Tracy CM, Epstein AE, Darbar D, Dimarco JP, Dunbar SB, Mark Estes NA 3rd, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg. 2012 Dec;144(6):e127-45. doi: 10.1016/j.jtcvs.2012.08.032.

27. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System-P010030. Accessed Dec 12, 2013. Available at URL address: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083949.htm

28. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. New Device Clearance. Philips HeartStart Home OTC Defibrillator. Accessed Dec 16, 2013. Available at URL address: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm080833.htm

29. Weisfeldt ML, Sitlani CM, Ornato JP, Rea T, Aufderheide TP, Davis D, et al.; ROC Investigators. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. J Am Coll Cardiol. 2010 Apr 20;55(16):1713-20

30. Zipes DP, Camm AJ, Borgrefe M, Buxton AE, Chaitman B, Fromer M, et al. American College of Cardiology; American Heart Association Task Force; European Society of Cardiology Committee for Practice Guidelines. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol. 2006 Sep 5;48(5):e247-346.