External Defibrillators

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Introduction

Wearable cardioverter-defibrillators (WCDs) and automated external defibrillators (AEDs) are addressed by this guideline.

Criteria

A **wearable cardioverter-defibrillator (WCD)** (HCPCS K0606) is medically necessary for individuals when **all** of the following apply:

- The individual has a documented history of **any** of the following conditions:
  - With each beat, the left ventricle sends ≤ 35% of its blood to the body due to damage to the heart muscle from a previous heart attack.
  - With each beat, the left ventricle sends ≤ 35% of its blood to the body due to stretched muscle fibers of the heart (dilated cardiomyopathy).
  - The individual had a period of at least 30 seconds when their ventricle was fibrillating, or beating very quickly, and not able to send enough blood to their body with each beat.
  - The individual has long QT syndrome or hypertrophic cardiomyopathy, which means their left ventricle is at risk of beating too fast and not being able to send enough blood to their body with each beat.
  - The individual cannot immediately have a permanent cardioverter-defibrillator placed because of an infection or a temporary situation (e.g waiting for a heart transplant).
  - The individual needs to have a cardioverter-defibrillator taken out and changed, but for health reasons, a new one cannot be put in right away.
- The individual has the mental and physical skills to respond to the device's alarms.
- The individual is able to use the device independently.

A **non-wearable automatic defibrillator** (HCPCS E0617) is medically necessary when an individual meets **both** of the following:

- There is documentation of **one** of the following conditions:
  - The individual cannot immediately have a permanent cardioverter-defibrillator placed because of an infection or a temporary situation (for example, waiting for a heart transplant), including **any** of the following:

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- The individual had a cardiac arrest where their ventricle was fibrillating and not able to send enough blood to their body with each beat.
- The individual had a period of at least 30 seconds when their ventricle was fibrillating, or beating very quickly, and not able to send enough blood to their body with each beat.
- The individual has long QT syndrome or hypertrophic cardiomyopathy, which means their left ventricle is at risk of beating too fast and is not able to send enough blood to their body with each beat.
- With each beat, the left ventricle sends less than or equal to 35% of its blood to the body due to damage to the heart muscle from a previous heart attack, and the ventricle fibrillates or beats very fast during an electrical study of the heart (EP) test. To meet this criterion:
  - It has been over four weeks since the heart attack; and,
  - There were at least four weeks between the heart attack and the EP test.
- With each beat, the left ventricle sends ≤ 35% of its blood to the body due to damage to the heart muscle from a previous heart attack when **none** of the following apply:
  - When in a steady baseline rhythm, the individual does not experience cardiogenic shock or symptoms of low blood pressure.
  - In the last three months, the individual has not had coronary artery bypass graft (CABG) surgery, and is not a current candidate for the procedure.
  - In the last three months, the individual has not had a coronary artery angioplasty procedure (percutaneous transluminal coronary angioplasty, or PTCA), and is not a current candidate for the procedure.
  - In the last 30 days, the individual has not had a heart attack with a blood test showing increased levels of cardiac muscle enzymes.
  - The individual does not have a terminal illness or life expectancy less than one year.
- With each beat, the left ventricle sends ≤ 35% of its blood to the body due to stretched muscle fibers of the heart from a previous attack (ischemic dilated cardiomyopathy), and the individual has limited heart function characterized by New York Heart Association (NYHA) Class II, III, or IV heart failure.
- The individual has non-ischemic dilated cardiomyopathy (NIDCM) for greater than three months with **both**:
  - NYHA Class II, III, or IV heart failure
  - Left ventricular ejection fraction (LVEF) ≤ 35%

◦ The individual needs to a have a previously implanted cardioverter-defibrillator (ICD) removed and changed, but for health reasons, a new device is unable to be implanted right away.

• There is a caregiver in the home who knows how to use the device.

DME Guidelines

Not Covered:

- For myocardial infarction without severe left ventricular dysfunction, evidence regarding use of WCDs is insufficient, conflicting, or poor, and demonstrates an incomplete assessment of net benefit versus harm. Additional research is recommended.
- When non-arrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in individuals who are not expected to survive greater than six months, use of WCDs is not medically necessary.

Rental Time Frames:

- Initial approval up to three-month rental.
- Authorization requests must include expected duration of need if anticipated to be over four months.
- One- to three-month approval for continued rental.
- Individual is re-assessed at least every three months for implantable cardioverter-defibrillator candidacy.
  - Re-evaluation of LVEF should occur one to three months after an MI.
  - If LVEF remains ≤ 35% on follow-up assessment while the individual is taking appropriate medical therapy, implantable cardioverter-defibrillator (ICD) placement may be considered medically necessary.
  - There is documentation to support the continued use of an automatic external defibrillator (AED) or wearable cardioverter-defibrillator (WCD) when permanent placement of an ICD is considered medically necessary, such as ongoing titration of medication to maximum efficacy.

Special Populations:

- Requests for individuals under 18 years of age are evaluated on a case by case basis due to limited evidence and United States Food and Drug Administration (FDA) approval considerations.
- The use of WCD devices in individuals who are pregnant or breastfeeding requires special and careful consideration. Treatment decisions for individuals who are pregnant or breastfeeding and otherwise meet criteria are based on member and provider shared decision making regarding risks and benefits.

Replacement Criteria:

- Replacement of a cardioverter-defibrillator and/or accessories is considered medically necessary when the device and/or accessories are damaged or malfunctioning, when replacement is recommended according to the manufacturer's instructions, or due to a change in the individual's medical condition.
- Replacement supplies and accessories for use with K0606 are coded using K0607, K0608, and K0609 as appropriate.

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- Replacement supplies and accessories for use with E0617 are coded using A9999.

Definitions

Automatic defibrillators are devices capable of detecting life-threatening cardiac dysrhythmias and delivering a defibrillation shock to the heart when appropriate to allow the heart to re-establish an effective rhythm.

A **wearable cardioverter-defibrillator (WCD)** is a non-invasive, electrode-based, vest-like device capable of automatic detection and defibrillation of ventricular tachycardia (VT) or ventricular fibrillation (VF).

A **non-wearable, automatic external defibrillator (AED)** is a portable device that uses externally placed electrodes for detection and defibrillation of VT or VF in an individual in cardiac arrest.

The **left ventricular ejection fraction (LVEF)** is a measurement of the amount of blood that the left ventricle of the heart is able to pump out into the body with each beat. The measurement is expressed as a percentage. An LVEF of approximately 50% to 70% is considered to be within normal range. An LVEF below 40% is considered to signal cardiac dysfunction, with an LVEF below 30% signaling severe dysfunction.

Heart failure (HF) is a common clinical syndrome with symptoms caused by impaired ability of one or both ventricles to pump at a normal pressure due to a structural or functional cardiac disorder. It is characterized by specific symptoms (e.g., dyspnea, fatigue) and signs (e.g., fluid retention).

The **New York Heart Association (NYHA)** has established a functional classification system for heart failure based on the timing of symptom onset for an individual.

- **Class I** heart failure is characterized by symptom onset with strenuous activity.
- **Class II** heart failure is characterized by symptom onset with an ordinary level of activity.
- **Class III** heart failure is defined as symptom onset with minimal activity, and is further broken down into:
  - **Class IIIa**, in which an individual has no shortness of breath at rest, or
  - **Class IIIb**, in which an individual has recent onset of shortness of breath at rest.
- **Class IV** heart failure is characterized by symptom onset at rest.

Dilated cardiomyopathy (DCM) is a disease of the heart muscle characterized by enlargement and dilation of one or both ventricles, as well as reduced LVEF (≤ 40%). Treatment and management of dilated cardiomyopathy follows heart failure treatment and management guidelines.

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Hypertrophic cardiomyopathy (HCM) is a genetic condition that causes increased left ventricular wall thickness (hypertrophy). This alteration of cardiac structure leads to left ventricular outflow obstruction, diastolic dysfunction, myocardial ischemia, and mitral regurgitation. Associated symptoms include fatigue, dyspnea, chest pain, palpitations, and syncope. Sudden cardiac death can occur, often in undiagnosed young athletes. Treatment and management may include diuretics, surgical myomectomy or alcohol septal ablation, mitral valve replacement, ICD and/or pacemaker placement, or heart transplant.

Ischemic cardiomyopathy (ICM) is the weakening of heart muscle due to prior myocardial infarction (MI) or chronic blockages of the coronary arteries.

Nonischemic cardiomyopathy (NICM) is left ventricular dilation and subsequent systolic dysfunction in the absence of significant coronary artery disease.

A **myocardial infarction (MI)** also known as a heart attack, occurs when the supply of oxygenated blood going to the heart muscle is blocked or severely reduced. The coronary arteries supply the heart muscle with oxygenated blood. When the coronary arteries are blocked, the heart muscle can deteriorate quickly, leading to cell death. If blood flow is not restored, the heart may stop beating.

Ventricular fibrillation (VF) is a type of arrhythmia in which the ventricles quiver asynchronously. VF can cause cardiac arrest and sudden cardiac death if not treated promptly. Patients with heart failure, CAD, and cardiomyopathy are at particular risk for VF. An implantable cardioverter-defibrillator (ICD), wearable cardioverter-defibrillator (WCD), or automated external defibrillator (AED) provides an electrical shock that can reset the heart rhythm and potentially save the life of the individual.

Ventricular tachycardia (VT) is defined as VT lasting greater than 30 seconds or requiring an intervention for termination (e.g., cardioversion, defibrillation).

Brugada syndrome is characterized by ST-segment elevation in the right precordial leads (i.e., type 1 electrocardiogram); these individuals have a propensity for ventricular arrhythmias and sudden cardiac death even with the presence of structurally normal hearts.

Long QT syndrome may be a congenital or acquired disorder characterized by a prolonged QT interval on electrocardiogram (ECG) in which delayed ventricular repolarization increases the risk for ventricular arrhythmias and sudden cardiac death (SCD).

Torsades de pointes is a form of polymorphic VT that classically occurs in the setting of acquired or congenital QT interval prolongation and typically has a rate between 160 and 250 beats per minute.

Sudden cardiac death (SCD) can be attributed to a number of causes. Common causes of SCD include coronary artery disease, cardiomyopathy, congenital anomalies

(e.g., tetralogy of Fallot, transposition of the great vessels), coronary artery anomalies, channelopathies (e.g., long QT syndrome, Brugada syndrome), and other causes (e.g., illicit and prescription drugs, blunt trauma to the chest).

An **implantable cardioverter-defibrillator (ICD)** is a small battery-powered device placed in the chest to detect and stop irregular heartbeats (arrhythmias) by electrical stimulation.

Evidence Discussion

Purpose of technology/description of device

The wearable cardioverter-defibrillator (WCD) functions in a similar manner to an automatic implantable cardioverter-defibrillator (ICD). The WCD is a vest that is worn under clothing, and consists of sensing electrodes, a continuously monitoring electrocardiogram, a microprocessor, an alarm module, and defibrillation electrodes. The WCD also includes a monitor pack, which houses the rechargeable battery, the patient response button, and a touch screen that allows the patient to capture and transmit information about their cardiac rhythm, engage in a 6-Minute Walk Test, and enter information to ascertain quality-of-life (QOL) indices.

Arrhythmia detection is technically challenging, as the four dry sensing electrodes are prone to skin motion artifact or loss of contact. This necessitates sophisticated compensatory algorithms to minimize false alarms and inappropriate therapy. After accounting for artifact, arrhythmia detection incorporates rate, stability, and template matching. There are two programmable zones with a customizable detection time and shock energy, but optimal device programming is not yet defined and is left to the discretion of the prescribing physician.

When the device senses a dysrhythmia, an alarm sounds. If the wearer of the vest fails to respond to the alarm, the defibrillation electrodes release a conductive gel and deliver an electrical shock of up to 150 joules with biphasic waveforms, with a response time of 25 to 180 seconds, as programmed by the physician. In addition to delivering therapeutic shocks for life-threatening ventricular arrhythmias, the WCD stores data regarding arrhythmias, patient compliance with the device, and noise or interference with its proper functioning. The vest is meant to be worn continuously, except when bathing or showering. WCDs are generally considered for use in patients who meet the criteria for an ICD, but who are not candidates for an ICD at the time of consideration. However, the device does not provide backup pacing and is contraindicated in patients with unipolar atrial or ventricular pacing due to problems with sensing arrhythmias in those contexts.

Automated external defibrillators (AEDs) are lightweight and portable, and can be found in many public areas, or obtained for home use with a valid prescription. These

devices may be fully automatic or semi-automatic. AEDs come with adhesive pads and a processing unit with a battery pack. With a fully automatic AED, the rescuer can affix the pads to the patient and step back. The fully automatic AED will deliver a shock if needed. With a semi-automatic device, the rescuer is required affix the pads, await instructions, then push a button on the processing unit to deliver a shock if needed. Some processing units have a simple interface with status lights, a speaker for voice prompts, and buttons for power control and shock administration. Other processing units may also come with an interactive video display that gives visual cues and step-by-step instructions.

Medical Background

Wearable cardioverter-defibrillators (WCDs):

WCDs were first evaluated for individuals at risk of sudden cardiac death in 1998, and received FDA approval in 2001 (Bhatt & Mittal, 2020). From 2001 until 2021, the ZOLL LifeVest® was the only commercially available device on the market in the United States. In 2021, the FDA approved the Kestra ASSURE system for use in adults who are at risk for sudden cardiac arrest and who are not candidates for, or who refuse, an ICD. The FDA considers WCDs to be Class III devices. Class III devices are those that support or sustain human life, and require pre-market approval, including stringent pre-market testing and data collection to establish safety and efficacy. LifeVest® and ASSURE are currently available for use in the United States.

The FDA has expanded the indications for use of a WCD to include pediatric individuals at risk for sudden cardiac arrest who are not candidates for, or who refuse, an ICD. However, the published literature on the use of WCDs in children is limited. Per FDA guidelines, pediatric individuals using a WCD must have a chest circumference of at least 66 centimeters (26 inches) and a weight of at least 18.75 kilograms (41.3 pounds).

Non-wearable automated external defibrillators (AEDs):

In 2015, the FDA instituted pre-market authorization requirements for AEDs. Manufacturers were given until 2022 to file pre-market approvals for their devices and accessories. Formerly considered Class II devices that required a less rigorous 510k approval process, AEDs are now required to go through a more rigorous pre-market approval process, and are considered Class III devices.

There are six FDA-approved AED devices available in the United States for home or public use as of early 2024, including the Defibtech Lifeline®, the HeartSine® Samaritan PAD, the Philips HeartStart® OnSite, the Physio Control LIFEPAK® (now sold manufactured by Medtronic®), the ZOLL AED®, and the ZOLL PowerHeart® (formerly manufactured by Cardiac Science®).

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Literature Review

Wearable cardioverter-defibrillators (WCDs):

- Poole et al. (2022) reported on a nonrandomized trial (ACE-DETECT) that assessed the ASSURE WCD (A-WCD) (Kestra Medical Technologies) false alarm rate, wear compliance, and adverse events (AEs) in ambulatory individuals. One hundred twenty-one individuals with a left ventricular ejection fraction ≤ 40% and an active implantable cardioverter defibrillator (ICD) were trained and used an A-WCD for 30 days with clinical follow up weekly by phone. The primary outcome measured the false positive shock alarm rate with a performance goal of one every 3.4 days. Additional outcomes measured included a summary of A-WCD and ICD detected episodes, patient-reported outcomes including perceived comfort, adverse events determined to be possibly related to use of the A-WCD, and patient wear compliance. Of 163 WCD episodes, four were ventricular tachycardia/ventricular fibrillation (VT/VF) and 159 non-VT/VF. Three false-positive shock alarm markers were recorded; one false-positive shock alarm every 1,333 patient days ($p<0.001$). No ICD recorded VT/VF episodes meeting WCD detection criteria (≥ 170 beats per minute for ≥ 20 seconds) were missed by the WCD during 3,501 patient days of use. Median wear was 31 days. Adverse events were mostly mild: skin irritation (19.4%) and musculoskeletal discomfort (8.5%). The authors concluded that the ASSURE WCD demonstrated a low false-positive shock alarm rate, low patient-reported discomfort, and no serious adverse events. However, the authors noted several limitations of the study, including a small sample size and short-term follow-up, which limited the generalizability of the results. Thus, additional prospective large studies were recommended.
- Olgin et al. (2018) conducted a randomized trial, the Vest Prevention of Early Sudden Death (VEST) trial, to evaluate whether a WCD would reduce arrhythmic death rates in individuals with recent acute myocardial infarction (MI) and an ejection fraction of 35% or less who were awaiting ICD insertion. One thousand five hundred twenty-four participants were randomly assigned to receive a WCD plus guideline-directed therapy (the device group) or to receive only guideline-directed therapy (the control group). 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 non-arrhythmic death. Arrhythmic death occurred in 1.6% of the participants in the device group and in 2.4% of those in the control group. Death from any cause occurred in 3.1% of the participants in the device group and in 4.9% of those in the control group, and non-arrhythmic death in 1.4% and 2.2%, respectively. The authors concluded that the WCD did not lead to a rate of arrhythmic death during the first 90 days that was significantly lower than the rate with guideline-directed medical therapy alone. However, the authors noted that the trial may have been underpowered to detect a beneficial effect of the WCD on the primary outcome.

- A systematic review and meta-analysis published by Masri et al. (2019) reported on the available evidence regarding the use of wearable cardioverter-defibrillators (WCDs). The study included 33,242 WCD users from 28 studies (the randomized Vest Prevention of Early Sudden Death (VEST) trial and 27 nonrandomized studies). The VEST trial was the first randomized trial that investigated the benefit of WCD use for individuals who suffered a myocardial infarction and had an LVEF ≤ 35% as compared to medical therapy only, and reported no difference in mortality secondary to sudden cardiac death. The incidence of appropriate shocks was 5 per 100 persons over three months (1.67 percent per month), with mortality while wearing the device noted to be 0.7 per 100 persons over three months. However, the authors noted several limitations, such as the inclusion of heterogeneous studies with variable inclusion criteria and mixed indications. Moreover, the majority of included studies were observational. The study concluded that more randomized controlled trials are needed to justify continued use of WCD in primary prevention.
- The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) (Bardy et al., 2005) randomly assigned 2,521 individuals with New York Heart Association (NYHA) Class II or III congestive heart failure (CHF) and a left ventricular ejection fraction (LVEF) of ≤35% to conventional therapy for CHF plus placebo (847 individuals), conventional therapy plus amiodarone (845 individuals), or conventional therapy plus a conservatively programmed, shock only, single-lead implantable cardioverter-defibrillator (ICD) (829 individuals). The primary end point was death from any cause. The authors found that a simple shock-only (ICD) reduced the overall risk of death by 23%, resulting in an absolute reduction of 7.2 percentage points at five years among individuals with CHF who received medical therapy, and the benefit did not vary according to the cause of CHF.
- Kutyifa et al. (2015) conducted a prospective study including 2,000 individuals with ischemic cardiomyopathy, non-ischemic cardiomyopathy, or congenital/inherited heart disease from the Wearable Defibrillator (WEARIT-II) Registry. Data including: arrhythmia events, implantable cardioverter -defibrillator (ICD) placement, and improvement in ejection fraction were recorded. The median wearable cardioverter-defibrillator (WCD) wear time was 90 days, with median daily use of 22.5 hours. There was a total of 120 sustained ventricular tachyarrhythmias in 41 participants, of whom 54% received appropriate WCD shock. The authors found a high rate of sustained ventricular arrhythmias at three months and concluded that use of a WCD is safe and effective for protecting these individuals against sudden cardiac death.
- The Defibrillators in Non-ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial (Kadish et al., 2004) evaluated the value of prophylactic implantable cardioverter-defibrillator (ICD) placement in individuals with non-ischemic dilated cardiomyopathy. Four hundred fifty-eight individuals with non-ischemic dilated cardiomyopathy, a left ventricular ejection fraction of < 36%, and premature ventricular complexes or non-sustained ventricular tachycardia were randomly assigned to receive standard medical therapy or medical therapy plus a single-chamber ICD. The mortality rate

at two years was 14.1% in the standard-therapy group, and 7.9% in the ICD group. The authors concluded that ICD insertion reduced the risk of sudden death from an arrhythmia in individuals with non-ischemic dilated cardiomyopathy. In addition, those individuals who had a recent diagnosis of non-ischemic dilated cardiomyopathy received the same benefits from ICD implantation as those with longstanding disease.

- Kondo et al. (2015) reported on a prospective study which evaluated the effectiveness of WCD in individuals with early post-myocardial infarction (MI). Twenty-four participants were followed-up for an average of eight months (range, 4-16 months). Two participants (8.3%) received appropriate shocks. Left ventricular ejection fraction improved after the WCD therapy. Fourteen participants (58%) received an ICD at the end of the follow-up period. Thus, the authors concluded that during the temporary waiting period post-MI, individuals who are at high risk of sudden cardiac death may benefit from time-limited WCD therapy.
- A retrospective study (Ellenbogen et al., 2017) reported on the time course of re-implantation and the benefits of WCD use in individuals post-ICD explantation. In a review of 8,058 individuals who were prescribed the WCD after ICD removal because of infection, median time to re-implantation was 50 days, and 334 (4%) individuals experienced 406 ventricular tachycardia/ventricular fibrillation (VT/VF) events. The investigators concluded that the WCD was highly effective in protecting individuals from VT/VF. As a result, the WCD may be considered as an alternative when re-implantation is medically delayed.
- Tanawuttiwat et al. (2014) performed a retrospective study to evaluate the effectiveness of WCD for sudden cardiac death (SCD) prevention in individuals who were discharged after ICD removal. Ninety-seven individuals who received a WCD following ICD removal due to device infection were included in the study. The median daily WCD use was 20 hours per day and the median length of use was 21 days. Two participants had four episodes of sustained VT which were successfully terminated by the WCD, while one participant received two inappropriate shocks due to signal artifact. Three participants experienced sudden death outside the hospital while not wearing the device. The authors concluded that a WCD may prevent SCD until re-implantation of an ICD is feasible, noting that compliance with the device is important.
- A registry analysis (Opreanu et al., 2015) evaluated the effectiveness of a WCD as a method of primary prevention of life-threatening ventricular arrhythmias and sudden cardiac death in individuals awaiting heart transplant. The study included 121 individuals awaiting heart transplant who wore a WCD for an average of 127 (±392) days with average daily use of 17 (±7) hours. Seven participants (6%) received appropriate WCD shocks. Fifty-one participants (42%) ended use after ICD implantation and 13 participants (11%) after heart transplantation. The authors concluded that the WCD is a reasonable bridge therapy for preventing sudden cardiac death in individuals with cardiomyopathy awaiting heart transplant, with high adherence and efficacy and low complication rates.

- Uyei and Braithwaite (2014) conducted a systematic review and meta-analysis to compare the efficacy of a WCD among specific groups, including post-myocardial infarction, post coronary artery bypass grafting or percutaneous coronary intervention, non-ischemic cardiomyopathy, and ischemic cardiomyopathy. The authors reviewed 33 studies and concluded that the use of a WCD reduced the absolute risk of sudden cardiac death due to ventricular tachycardia or ventricular fibrillation by approximately 1%, as compared with no defibrillator use, which was achieved by averting approximately 80% of all such deaths. However, none of the included studies were randomized trials and thus, the authors reported a low to very low quality of evidence.

Non-wearable automated external defibrillators (AEDs):

- Bardy et al. (2008) conducted a randomized trial to determine whether an AED in the home of individuals with an intermediate risk of sudden cardiac arrest could improve survival. Seven thousand one individuals with a previous anterior-wall Q-wave or non-Q-wave myocardial infarction (MI) at 178 clinical sites in seven countries were randomized to receive one of two responses after a cardiac arrest occurring at home: the control response which included calling emergency medical services (EMS) and performing cardiopulmonary resuscitation (CPR), or the use of an AED followed by calling EMS and performing CPR. The primary outcome was death from any cause. Individuals who were candidates for an ICD were excluded from the study. The median follow-up was 37.3 months. A total of 450 individuals died: 228 of 3,506 (6.5%) in the control group, and 222 of 3,495 patients (6.4%) in the AED group. 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. The authors concluded that access to a home AED did not significantly improve overall survival for this intermediate risk population, compared to reliance on conventional resuscitation methods. However, AEDs resulted in long-term survival for six individuals (33%). The authors noted that the high proportion of unwitnessed events and under use of the AEDs in emergencies, rather than a lack of device efficacy, appear to explain these results.
- The Public Access Defibrillation (PAD) Trial (Hallstrom et al., 2004), a prospective multicenter trial, was designed to determine whether the rate of survival would increase if laypersons were trained to attempt defibrillation with the use of AEDs. Community facilities (e.g., shopping malls, recreation centers, hotels, and apartment complexes) were recruited to participate. The primary outcome was survival to hospital discharge. There were more survivors to hospital discharge in units assigned to have volunteers trained in CPR plus the use of AEDs than in the group assigned to have volunteers trained only in CPR. However, when the data for cardiac arrests that occurred in residential units and public units are examined separately, there

was no demonstrated survival benefit of CPR plus AED in residential patients. 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. Moreover, trained laypersons can use AEDs safely and effectively. However, caution must be used when these results are extrapolated to broad, nationwide efforts.

Pediatric population:

- Collins et al. (2010) performed a retrospective review to compare the use of a WCD in 81 individuals ≤18 years old and 103 individuals ages 19-21 years old who were at high risk of sudden cardiac death. Cardiomyopathy and primary arrhythmia were the most common underlying diagnoses in both groups. In addition, congenital heart disease was more common in the group of participants ages ≤18 years old. There was no difference between groups in the average hours of device use per day or in the total number of days the participants wore the defibrillator. In participants ≤18 years of age, there was one inappropriate therapy due to sinus tachycardia and one withholding of therapy due to a device-device interaction with a unipolar pacemaker. In participants aged 19-21 years, there were five appropriate discharges in two participants and one inappropriate discharge in a single patient. There were no appropriate shocks administered in the ≤ 18 years of age group, thus the true efficacy of the WCD for this population cannot be assessed. The largest category for discontinuation of the WCD was transition to a permanent ICD. Noncompliance or reports of the device being uncomfortable occurred in 6 out of 81 (7%) of the participants ≤18 years old, and in 11 out of 103 (11%) of the participants aged 19-21 years. Thus, the authors concluded that while the pediatric population and young adult population were similar in terms of adherence with a WCD, the study was inconclusive regarding the efficacy of the WCD in the pediatric population. However, the authors suggested that it is reasonable to consider the WCD as a therapy for pediatric individuals who are at high risk of sudden cardiac arrest but who have contraindications to, or would like to defer, placement of a permanent ICD.In addition, the authors reported that noncompliance with the device is an important consideration when prescribing the WCD.
- Spar et al. (2018) conducted a retrospective review that assessed the effectiveness, safety, and compliance with the WCD in the identification and treatment of life-threatening ventricular arrhythmias in pediatric individuals. Four hundred fifty-five individuals <18 years old using a WCD were divided into two groups: WCD use due to an ICD problem (n=63) and any other indication for the WCD due to a non-ICD problem (n=392). A successful therapy was defined as terminating VT or VF. The wear duration in days was significantly shorter in the ICD problem group compared with the non-ICD problem group (26 days versus 35 days). There were eight participants that received therapy from WCD, and six of the eight participants received appropriate therapies. The inappropriate therapies were secondary to

over sensing of artifact during asystole (n=1) and noise/artifact during sinus rhythm (n=1). There were seven deaths (1.5 percent); none were wearing the WCD at the time of death. The authors concluded that the WCD is safe and effective in treating ventricular arrhythmias that can lead to sudden cardiac death in pediatric individuals.

- McLeod et al. (2017) conducted a retrospective review of AED use in children at potential increased risk of arrhythmic sudden death. Thirty-six AEDs were issued to children ages one day to 15 years (mean age 8.8 years). Follow-up ranged from 12 to 138 months, with a median of 50 months (4.1 years) and a mean of 75.5 months (6.2 years). Diagnoses at issue included long QT syndrome (50%), broad complex tachycardia (14%), hypertrophic cardiomyopathy (11%), and catecholaminergic polymorphic ventricular tachycardia (9%). During the study period, the AED was used in four (9%) children, and in all four, the AED correctly discriminated between a shockable rhythm, polymorphic ventricular tachycardia/ventricular fibrillation (n=3) and non-shockable rhythm (n=1). Of the three children, two who received one or more shocks for ventricular fibrillation/polymorphic ventricular tachycardia survived, and one died as a result of recurrent torsades de pointes. There were no other deaths. The authors concluded that prescribing an AED should be considered for children at increased risk of sudden arrhythmic death, especially where the risk/benefit ratio of an implantable defibrillator is unclear or delay of defibrillator implantation is deemed necessary.

Professional organizations/societies:

- The American Heart Association (AHA) Science Advisory on wearable cardioverter-defibrillator (WCD) therapy for the prevention of sudden cardiac death (Piccini et al., 2016) included the following recommendations for WCD therapy:
  - Class IIa ("It is reasonable to perform procedure/administer treatment; the benefit outweighs the risk, but additional studies with focused objectives are needed."):
    - Use of wearable defibrillators is reasonable when there is a clear indication for an implantable cardioverter-defibrillator (ICD) accompanied by a transient contraindication or interruption in ICD care such as infection. (Level of Evidence: C)
    - Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation. (Level of Evidence: C)
  - Class IIb ("Procedure/Treatment may be considered; additional studies with broad objectives are needed; additional registry data would be helpful."):
    - WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce sudden cardiac death (SCD) but not overall survival, such as within 40 days of myocardial infarction (MI). (Level of Evidence: C)

        - Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time, or for treatment of left ventricular dysfunction, for example, in ischemic heart disease with recent revascularization, newly diagnosed non-ischemic dilated cardiomyopathy in a patient starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable. (Level of Evidence: C)
    - Class III Level C ("Procedure is not useful/effective and may be harmful; only expert opinion, case studies, or standard of care."):
        - WCDs should not be used when non-arrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months. (Level of Evidence: C)
- The American Heart Association, American College of Cardiology, and Heart Rhythm Society Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, et al., 2017) provided the following recommendations for a wearable cardioverter-defibrillator (WCD):
    - Class IIa (Moderate) Benefit >> Risk:
        - In patients with an implantable cardioverter-defibrillator (ICD) and a history of sudden cardiac arrest or sustained ventricular arrhythmia in whom removal of the ICD is required (as with infection), the WCD is reasonable for the prevention of sudden cardiac death (SCD).
    - Class IIb (Weak) Benefit > Risk:
        - In patients at an increased risk of SCD who are not ineligible for an ICD, such as awaiting cardiac transplant, having a left ventricular ejection fraction of 35% or less and are within 40 days from a myocardial infarction, or have newly diagnosed non-ischemic cardiomyopathy, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy, or a systemic infection, WCD may be reasonable.
- A Specialty society guideline consensus statement from an international collaboration among 10 professional organizations, including the Heart Rhythm Society, American College of Cardiology, American Heart Association, Asia Pacific Heart Rhythm Society, American Society of Anesthesiologists, European Heart Rhythm Association, Infectious Diseases Society of America, Latin American Heart Rhythm Society, Pediatric and Congenital Electrophysiology Society, and Society of Thoracic Surgeons (Kusumoto et al., 2017) stated that a wearable cardioverter-defibrillator is reasonable for the prevention of sudden cardiac death in individuals with a history of sudden cardiac arrest or sustained ventricular arrhythmia in whom removal of an existing implantable cardioverter-defibrillator is required.
- The American College of Cardiology/American Heart Association/Heart Rhythm Society Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

(Epstein et al., 2012) reported that ICD therapy is recommended for an individual with:

- History of unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes (Level of Evidence: A)
- Structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable (Level of Evidence: B)
- Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study (Level of Evidence: B)
- A LVEF less than or equal to 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III (Level of Evidence: A)
- Non-ischemic DCM who has an LVEF less than or equal to 35% and who are in NYHA functional Class II or III (Level of Evidence: B)
- LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I (Level of Evidence: A)
- Non-sustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study (Level of Evidence: B)

Codes addressed in this guideline

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

HCPCS Code	Description
A9999	Miscellaneous DME supply or accessory, not otherwise specified
E0617	External defibrillator with integrated electrocardiogram analysis
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each

HCPCS Code	Description
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

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