

External Defibrillators

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Introduction

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

Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Criteria

A **wearable cardioverter-defibrillator (WCD)** (HCPCS K0606) is considered 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 $\leq 35\%$ 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 $\leq 35\%$ 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 considered 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:
 - 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 $\leq 35\%$ 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 $\leq 35\%$ 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) $\leq 35\%$
- The individual needs to 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.

Special Populations

- Requests for individuals under 18 years of age are evaluated on a case by case basis due to limited clinical evidence and U.S. Food and Drug Administration (FDA) approval constraints for pediatric populations.
- 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.

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 considered 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
- Renewal approvals may be granted in one- to three-month increments based on clinical documentation supporting ongoing need.
- The individual must be re-assessed at least every three months to determine candidacy for permanent implantable cardioverter-defibrillator (ICD) placement..

- Re-evaluation of LVEF should occur one to three months after a myocardial infarction (MI).
- If LVEF remains $\leq 35\%$ on follow-up assessment while the individual is taking appropriate medical therapy, 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.

Replacement Criteria

- Replacement of a cardioverter-defibrillator device and/or its accessories is considered medically necessary when **any** of the following apply:
 - The device or accessories are damaged or malfunctioning.
 - Replacement is recommended by the manufacturer.
 - Replacement is required due to a change in the individual's medical condition that affects device suitability or functionality.
- Replacement supplies and accessories for use with K0606 are coded using K0607, K0608, and K0609 as appropriate.
- Replacement supplies and accessories for use with E0617 are coded using A9999.

Background and Supporting Information

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 (Ferrer, 1979).

- **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

Evidence Discussion

A 2026 observational cohort study (Andersen et al.) showed that AEDs used in private homes improved outcomes for individuals who experienced out of hospital cardiac arrest with a shockable rhythm, with survival to hospital discharge increasing from 21.7% without an AED to 28.3% with an AED, representing a relative survival increase of 26%. Favorable neurological outcomes also improved, rising from 18.3% to 25.2% in those with a shockable rhythm when an AED was applied. These findings supported the clinical advantage of having immediate access to a defibrillator in the home, where most cardiac arrests occur and where emergency response times tend to be longer. Limitations included the rarity of AED use in private homes, which resulted in small sample sizes, wide confidence intervals, and reliance on observational data with assumptions that could not be fully validated, although sensitivity analyses suggested that these uncertainties did not meaningfully change the overall conclusions.

A 2025 systematic review and meta-analysis by Matteucci et al. evaluated 40 studies (n=59647) of adult individuals who used a wearable cardioverter defibrillator and found that the device appropriately terminated life-threatening ventricular tachycardia or ventricular fibrillation in 3% of users, with a prediction interval ranging from 1%-8%. Effectiveness was greatest in the early high-risk period, defined as the first 60 days of use, when arrhythmic events occurred more frequently. Consistent daily wear time significantly influenced successful intervention, and demographic factors such as age, sex, and ejection fraction did not modify outcomes. The findings supported the use of wearable defibrillation technology in the home setting, as it provided continuous physiologic surveillance and timely arrhythmia-specific therapy for individuals who remained at elevated risk for sudden cardiac arrest yet were not immediate candidates for an implantable device. However, the analysis noted some limitations, including substantial heterogeneity across studies and inconsistent evidence on optimal individual selection and timing of benefit. Additionally, the dependence on individual adherence introduced variability that could affect real-world performance.

A 2025 review (Duncker et al.) summarized current evidence on the use of wearable cardioverter defibrillators for sudden cardiac death prevention and heart failure management. The WCD provided continuous rhythm surveillance and automatic shock delivery for ventricular tachycardia or ventricular fibrillation, functioning as a non-invasive bridge during periods when implantable devices were not indicated or were temporarily deferred. The authors emphasized that the device offered immediate therapy in the home environment, allowing individuals to remain protected while undergoing diagnostic evaluation or awaiting recovery of ventricular function. Limitations included gaps in the evidence base, such as reliance on heterogeneous observational data and incomplete clarity on optimal individual selection, which indicated that further research was still needed to refine clinical use.

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 $\leq 40\%$ 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. 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.

Pediatric Population

A 2020 analysis (Evers et al.) showed that using a WCD at home provided meaningful protection for individuals with pediatric dilated cardiomyopathy during the three month medical optimization period before implantable cardioverter defibrillator placement. The home WCD strategy increased survival to the end of the optimization period to 88.6% compared with 84.5% for those discharged home without arrhythmia protection, and it prevented four additional deaths per 100 individuals when compared with no WCD. Lifetime quality adjusted survival also improved, with WCD yielding 42.58 quality adjusted life years versus 40.63 for no WCD. Mortality outcomes for WCD were nearly equivalent to inpatient continuous monitoring, demonstrating that home use allowed individuals to avoid prolonged hospitalization while maintaining similar arrhythmia protection benefits. Study limitations included uncertainty around the true probability of sudden cardiac arrest and survival in each care environment, since these inputs were derived from heterogeneous sources and not directly measured in pediatric individuals with dilated cardiomyopathy, which may have influenced modeled outcomes.

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.

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.

HCPSC 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

HCP Code	Description
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

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