Wearable Defibrillators - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: May 28, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Wearable Defibrillators (Single Service)

Literature review current through: 5/28/2024
Document last updated: 5/28/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Wearable Defibrillator

General Guidelines

- **Units, Frequency, & Duration:** One instance, as needed per inclusion criteria.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** A wearable cardioverter-defibrillator (WCD) is an external device worn as a garment capable of automatic detection and treatment of ventricular tachycardia (VT) or ventricular fibrillation (VF). There are patients at high risk for ventricular arrhythmias and sudden cardiac death who may not be ideal candidates for an implanted device for the following reasons[1]:
    - Susceptibility to life-threatening ventricular arrhythmias may be short-lived (e.g., after recovery from acute MI or myocarditis)
    - An implanted device may interfere with future interventions (e.g., cardiac transplantation)
    - When a systemic infection prevents the insertion of an ICD
- **Exclusions:** Wearable defibrillators should not be requested if an implantable cardioverter-defibrillator is in place and functional.[2,3]

Medical Necessity Criteria

Indications

➔ **Wearable Defibrillators** are considered appropriate if **ALL** of the following are **TRUE**:

◆ **ANY** of the following[4]:

- Aborted sudden cardiac arrest, when an ICD is inaccessible or transiently contraindicated (e.g., systemic infection); **OR**
- LVEF less than or equal to 35% after a recent MI during the 40-day ICD waiting period; **OR**
- After coronary artery bypass surgery (CABG) or percutaneous coronary intervention with LVEF less than or equal to 35% during the 90-day ICD waiting period; **OR**
- In a patient listed for cardiac transplant; **OR**
- Recently diagnosed nonischemic cardiomyopathy with LVEF less than or equal to 35% during the 3-month waiting period[1,5]; **OR**

- Myocarditis or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable; **OR**
- During an interval when an ICD requires removal (e.g., device pocket infection, endocarditis)[1]; **AND**

◆ Any patient less than 18 years of age must have a chest circumference of 26 inches (66 centimeters) or greater and a weight of 41.3 pounds (18.75 kilograms) (ZOLL LifeVest).[2]

Non-Indications

➔ **Wearable Defibrillators** are **NOT** considered appropriate if **ANY** of the following is **TRUE**[2-4]:

◆ When an active implantable defibrillator is in place; **OR**
◆ In a patient who is a candidate for an implantable cardioverter-defibrillator (ICD); **OR**
◆ VT that is amenable to catheter ablation; **OR**
◆ Terminal disease with a life expectancy of less than 1 year.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code 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
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified healthcare professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745	Initial set-up and programming by a physician or other qualified healthcare professional of wearable

	cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

Medical Evidence

Piccini et al. (2016) developed a science advisory for the American Heart Association for wearable cardioverter-defibrillator (WCD) therapy for the prevention of sudden cardiac death. They state that there is a paucity of prospective data (published, randomized clinical trials) supporting the use of the WCD. Though early implantable cardioverter-defibrillator (ICD) placement does appear to decrease the incidence of sudden cardiac death, overall survival benefit early after myocardial infarction (MI) or new cardiomyopathy diagnosis has not been proven. Wearable defibrillators are useful in the immediate post-MI period, when an implantable defibrillator may be postponed due to the potential of myocardial recovery and improved ventricular function.[1]

Duncker and Veltmann performed a systematic review in 2016 of wearable cardioverter defibrillators. It is stated that a relevant proportion of patients receiving an ICD do not meet evidence-based criteria for implantation. A study of 91 patients after MI found that 45% of patients met ICD criteria of left ventricular ejection fraction less than or equal to 35% 40 days after MI. Six of the patients significantly improved by 3 months of follow-up. The study determined that patients with recent onset non-ischemic cardiomyopathy showed no benefit from early ICD implantation.[4]

The 2017 AHA/ACC/HRS guideline for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. [2018]) contains two definite recommendations for WCDs. In the case of a patient with an ICD, a history of sudden cardiac arrest or sustained ventricular arrhythmia, and infection or other cause necessitating ICD removal, the WCD is recommended. The second recommendation is for patients at increased risk for sudden cardiac death, but who are not ineligible for an ICD, such as awaiting cardiac transplant or having an LVEF of 35% or less, and are within 40 days from an MI. This group of patients may also have newly diagnosed non-ischemic cardiomyopathy (NICM), revascularization within the past 90 days, myocarditis, secondary cardiomyopathy, or systemic infection, and thereby would be recommended for WCD.[5]

References

1. Piccini JP Sr, Allen LA, Kudenchuk PJ, et al. Wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death: a science advisory from the American Heart Association. *Circulation*. 2016; 133:1715.
2. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED). LifeVest Wearable Cardioverter Defibrillator. December 17, 2015. https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030s056b.
3. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED). ASSURE Wearable Cardioverter Defibrillator (WCD) System (ASSURE system). July 28, 2021. https://www.accessdata.fda.gov/cdrh_docs/ pdf20/P200037B.
4. Duncker D, Veltmann C. The wearable cardioverter/defibrillator - toy or tool?. *J Atr Fibrillation*. 2016;8(6):1367. Published 2016 Apr 30. doi:10.4022/jafib.1367
5. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline 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 on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* 2018; 72:e91.

Clinical Guideline Revision History/Information

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Review History	