



## **Cohere Medical Policy - Wearable Defibrillators**

*Clinical Policy for Medical Necessity Review*

**Version: 2.1**

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Next Annual Review: July 31, 2026

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## Policy Information:

**Specialty Area:** Cardiovascular Disease

**Policy Name:** Cohere Medical Policy - Wearable Defibrillators

**Type:**  Adult (18+ yo) |  Pediatric (0-17 yo)

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# Medical Necessity Criteria

## **Service: Wearable Defibrillators**

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
  - The medical necessity of each individual request
  - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
  - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

## **Description**

A wearable defibrillator or wearable cardioverter-defibrillator (WCD) is an external defibrillator device worn as a garment that monitors a patient's heart rhythm. It is capable of automatic detection and treatment of ventricular tachycardia (VT) or ventricular fibrillation (VF). WCDs are designed to be worn as temporary, short-term devices for 3 months or less.<sup>1</sup> Since the first WCD was approved by the U.S. Food and Drug Administration (FDA) over two decades ago, other WCDs have obtained FDA approval.<sup>2-4</sup>

## **Medical Necessity Criteria**

### **Indications**

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

- **ANY** of the following<sup>2,5-6</sup>:
  - There is a clear indication for an ICD, but an ICD is inaccessible or transiently contraindicated (e.g., systemic infection)<sup>5</sup>; **OR**
  - Left ventricular ejection fraction (LVEF) less than or equal to 35% after a recent myocardial infarction (MI) during the 40-day ICD waiting period<sup>6</sup>; **OR**
  - After coronary artery bypass surgery or percutaneous coronary intervention with LVEF less than or equal to 35% during the 90-day ICD waiting period<sup>6</sup>; **OR**
  - The patient is listed for cardiac transplant<sup>6</sup>; **OR**
  - Recently diagnosed nonischemic cardiomyopathy with LVEF less than or equal to 35% during the 3-month waiting period<sup>5-6</sup>; **OR**
  - Myocarditis or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) in which the underlying cause is potentially treatable<sup>5</sup>; **OR**
  - During an interval when an ICD requires removal (e.g., device pocket infection, endocarditis)<sup>6</sup>; **AND**
- **ANY** of the following:
  - The patient is greater than or equal to 18 years of age; **OR**
  - The patient is less than 18 years of age, and **ALL** of the following<sup>2</sup>:
    - The request is for ZOLL LifeVest<sup>2</sup>; **AND**
    - The patient has a chest circumference greater than or equal to 26 inches (66 centimeters)<sup>2</sup>; **AND**

- The patient weighs more than or equal to 41.3 pounds (18.75 kilograms).<sup>2</sup>

Monthly monitoring of the device (CPT 93292) is considered appropriate if **ALL** of the following are **TRUE**:

- The request is within the waiting period.

### Non-Indications

**Wearable Defibrillators** are not considered appropriate if **ANY** of the following is **TRUE**<sup>2,5</sup>:

- When an active implantable defibrillator is in place<sup>2</sup>; **OR**
- In a patient who is a candidate for an implantable cardioverter-defibrillator (ICD)<sup>2</sup>; **OR**
- VT that is amenable to catheter ablation; **OR**
- Terminal disease with a life expectancy of less than 6 months<sup>5</sup>; **OR**
- The request is for monthly monitoring of the device beyond the length of time of the waiting period.

### 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

In 2025, a patch-WCD received FDA premarket approval. The Jewel patch-WCD was designed to overcome and address the limitations associated with traditional garment-based WCDs in two areas: poor patient compliance and inappropriate detections and false alarms. First, the device is water-resistant and can be worn almost all the time, even while the patient is in the shower, which could improve patient compliance. Second, the software has a machine learning detection algorithm designed to improve detection and protection against sudden cardiac arrest.<sup>4</sup>

Hummel et al. (2024) published the results of the Jewel investigational device exemption (IDE) study, which assessed the safety and effectiveness of the patch-WCD for monitoring, detecting, and terminating sustained VT/VF. The multicenter, prospective, single-arm study enrolled 305 patients typically indicated for WCDs, who were not candidates for or refused an implantable defibrillator. Of all patients studied for the safety endpoint of <15% (to be in line with the incidence of skin-related adverse events for other commercially available WCDs), only 2.30% experienced a clinically significant cutaneous adverse event, and all clinically significant cutaneous adverse events were moderate in severity. In the current study, false alarms and inappropriate shock rates were low, which is important because Dang et al. (2024) showed that false alarms lead to sleep interruption, patient noncompliance, and generate anxiety.<sup>10</sup> Also, they showed the effective detection and conversion of shockable events. No false alarms were experienced in 61.7% of patients, compared to only 28.3% patients who had no false alarms with the LifeVest WCD. This IDE study met the primary and secondary effectiveness and safety endpoints, and no patient deaths or device missed episodes that required external rescue. The high median wear time compliance of 23.5 hours/day exceeded the secondary endpoint of wear time compliance of >14.1 hours/day, resulting in a high number of successful lifesaving conversions.<sup>8</sup>

Olgin et al. (2018) conducted a trial to determine the efficacy of WCDs in preventing arrhythmic and all-cause mortality. The VEST trial (Vest Prevention of Early Sudden Death Trial) was a multicenter, randomized, controlled trial that evaluated 2,302 patients with an acute myocardial infarction and ejection fraction <35% during the period before ICDs were indicated. Two-thirds of the patients received a WCD plus guideline-directed therapy

(the device group), while one-third of the patients received only guideline-directed therapy (the control group). They found that treatment with a WCD did not result in a significantly lower rate of arrhythmic death than guideline-directed therapy only during the first 90 days. Importantly, this study was conducted several years ago when there was only one WCD device on the market.<sup>9</sup>

Piccini et al. (2016) developed a science advisory for the American Heart Association for 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 ICD placement does appear to decrease the incidence of sudden cardiac death, overall survival benefit early after 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.<sup>5</sup>

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.<sup>7</sup>

The 2017 AHA/ACC/HRS guideline for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death contains two definite recommendations for WCDs. The first WCD recommendation is for patients with an ICD, a history of sudden cardiac arrest or sustained ventricular arrhythmia, and infection or other cause necessitating ICD removal. 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 of an MI. This group of patients may also have newly diagnosed non-ischemic cardiomyopathy, revascularization within the past 90 days, myocarditis, secondary cardiomyopathy, or systemic infection, and thereby would be recommended for a WCD.<sup>6</sup>

## References

1. Cheung CC, Olgin JE, Lee BK. Wearable cardioverter-defibrillators: A review of evidence and indications. *Trends Cardiovasc Med*. 2021 Apr;31(3):196–201. doi: 10.1016/j.tcm.2020.03.002. Epub 2020 Mar 12. PMID: 32205034
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.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030s056b.pdf)
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.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200037B.pdf)
4. US Food and Drug Administration. Premarket Approval (PMA). Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) (Jewel). Published April 30, 2025.  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230022>
5. 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 Apr 26;133(17):1715–27. doi: 10.1161/CIR.0000000000000394. Epub 2016 Mar 28. PMID: 27022063
6. 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: Executive summary: 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 Oct 2;72(14):1677–1749. doi: 10.1016/j.jacc.2017.10.053. Epub 2017 Oct 30. Erratum in: *J Am Coll Cardiol*. 2018 Oct 2;72(14):1756–1759. doi: 10.1016/j.jacc.2018.08.2131. PMID: 29097294

7. Duncker D, Veltmann C. The wearable cardioverter/defibrillator – Toy or tool? *J Atr Fibrillation*. 2016 Apr 30;8(6):1367. doi: 10.4022/jafib.1367. PMID: 27909495; PMCID: PMC5089470
8. Hummel J, Houmsse M, Tomassoni G, et al. A patch wearable cardioverter-defibrillator for patients at risk of sudden cardiac arrest. *J Am Coll Cardiol*. 2024 Aug 6;84(6):525–536. doi: 10.1016/j.jacc.2024.04.063. PMID: 39084827
9. Olgin JE, Pletcher MJ, Vittinghoff E, et al. Wearable cardioverter-defibrillator after myocardial infarction. *N Engl J Med*. 2018 Sep 27;379(13):1205–1215. doi: 10.1056/NEJMoa1800781. PMID: 30280654; PMCID: PMC6276371
10. Dang PL, Lacour P, Parwani AS, et al. False alarms in wearable cardioverter defibrillators – A relevant issue or an insignificant observation. *J Clin Med*. 2024 Dec 19;13(24):7768. doi: 10.3390/jcm13247768. PMID: 39768691; PMCID: PMC11728023

# Policy Revision History/Information

Original Date: May 28, 2024		
Review History		
Version 1	05/28/2024	New policy.
Version 2	07/31/2025	<p>Annual review.</p> <p>Added new Description section.</p> <p>Indication language was revised for clarity.</p> <p>Changed non-indication to "Terminal disease with a life expectancy of less than 6 months" (previously 1 year). Corrected as stated in reference #5, Piccini et al.</p> <p>Added new indication, "The request is for monthly monitoring of the device within the waiting period," and added related non-indication, " The request is for monthly monitoring of the device beyond the length of time of the waiting period."</p> <p>Pediatric LifeVest indication restructured without altering the medical necessity criteria.</p> <p>Additional citations were added throughout the indications section. No changes to the procedure codes.</p> <p>Medical Evidence - Added the new Jewel patch-WCD recently approved by the FDA</p>

		<p>(2025), as well as the investigational device exemption (IDE) study for this device. Added information on the VEST trial (Vest Prevention of Early Sudden Death Trial) (Olgin et al., 2018), which was missing in the previous version.</p> <p>References section updated (Cheung et al., 2021; USDA Jewel Patch Wearable Cardioverter Defibrillator, 2025; Hummel et al., 2024; Olgin et al., 2018; and Dang et al., 2024).</p>
Version 2.1	11/04/2025	Clarified boolean logic structure. No indications or non-indications changes.