Molina Clinical Policy
Wearable Cardioverter-Defibrillator Devices
Policy No. 451

Last Approval: 04/08/2026
Next Review Due By: April 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

A **wearable cardioverter-defibrillator (WCD) device** is an external device capable of automatically detecting and treating ventricular tachycardia or ventricular fibrillation (Chung 2025). The system consists of a fitted garment worn under clothing that contains electrocardiogram sensors and defibrillation pads, which connect to a programmable monitor typically worn at the waist. This monitor continuously analyzes cardiac rhythms and issues alerts or alarms when potentially life-threatening ventricular arrhythmia is detected. If indicated, the device delivers a shock, although a conscious patient may abort therapy by pressing and holding the response button. According to ZOLL Medical Corporation (2024), the sequence from arrhythmia detection to shock delivery occurs in approximately one minute. WCDs do not provide pacing in the event of bradycardia but can alert the patient if bradycardia is detected; the ASSURE device additionally emits a loud alarm instructing bystanders to call emergency services and initiate cardiopulmonary resuscitation if asystole occurs. All rhythm data and therapy events are recorded on the monitor and can be transmitted electronically to the care team. Prior to use, patients undergo individualized fitting and training on device assembly, daily wear, alarm response, and data transmission via modem or smartphone application (Chung 2025; Kestra Medical Technologies 2024; ZOLL Medical Corporation 2025).

A WCD device is generally for patients at high risk for sudden cardiac death when immediate placement of an implantable cardioverter-defibrillator (ICD) is not feasible. Common reasons for deferring ICD implantation include active infection, early post-myocardial infarction, recent surgery, lack of vascular access, new-onset systolic heart failure, or limited life expectancy. Additional indications include ICD explantation due to malfunction or infection, or use as temporary protection in patients with severe heart failure awaiting heart transplantation. WCDs serve as a short-term “bridge therapy”, typically worn for up to three months, although extended use may be appropriate depending on clinical progression. Patient compliance with WCD device usage is integral to successful therapy and it is recommended that patients wear the WCD device continuously, day and night, with removal only for activities such as bathing and swimming (Al-Khatib et al. 2017; Chung 2025).

Regulatory Status

There are currently two WCD devices approved by the U.S. Food and Drug Administration (FDA): the ZOLL LifeVest (PMA P010030) and the Kestra Medical Technologies ASSURE (PMA P200037). The LifeVest was originally approved on December 18, 2001, as the first FDA-cleared WCD for patients at risk of sudden cardiac arrest who were not candidates for an implantable defibrillator (FDA 2001). It later received expanded approval for pediatric use in patients with a chest circumference ≥26 inches (66 cm) and weight ≥18.75 kg (FDA Supplement S056, 2015). The Kestra ASSURE WCD system received original FDA approval on July 27, 2021, and has since undergone multiple PMA supplements (FDA 2021). Additional information about device updates, FDA supplements, and regulatory notices may be reviewed by searching product code “MVK” in the FDA Premarket Approval database.

COVERAGE POLICY

Wearable cardioverter-defibrillator devices may be **considered medically necessary** for an initial 90-day period when ALL the following criteria are met:

1. Member has a chest circumference ≥ 26 inches (66 centimeters) and weighs ≥ 41.3 pounds (18.75 kilograms)

2. Member is at high-risk for sudden cardiac death and placement of an implantable cardioverter-defibrillator must be delayed for ONE of the following reasons:
    a. Member is awaiting implantable cardioverter defibrillator placement, or an existing implantable cardioverter defibrillator must be explanted, and immediate placement or re-placement is not possible (e.g., due to infection)
    b. Member is awaiting a cardiac transplant
    c. The risk of sudden cardiac death which may resolve over time or with treatment, as indicated by ONE or more of the following:
        i. Ischemic heart disease with an ejection fraction ≤ 35% and ONE or more of the following:
            1. Recent (≤ 40 days) myocardial infarction
            2. Revascularization (e.g., coronary artery bypass graft) within the last 90 days
        ii. Cardiomyopathy as evidenced by ONE of the following:
            1. Acute myocarditis as indicated by ONE or more of the following:
                a. Member has an ejection fraction ≤ 35% and has received < 3 months of optimal goal directed medical therapy or magnetic resonance imaging findings of inflammation
                b. History of sudden cardiac arrest
                c. Sustained ventricular arrhythmias
            2. Non-ischemic dilated cardiomyopathy and ALL the following:
                a. Member has an ejection fraction ≤ 35%
                b. Member has received < 3 months of optimal goal directed medical therapy*
            3. Peripartum cardiomyopathy with an ejection fraction ≤ 35%
            4. Secondary cardiomyopathy with an ejection fraction ≤ 35% and a potentially treatable underlying cause (e.g., tachycardia-mediated, thyroid-mediated)

3. Member agrees to be compliant with therapy (e.g., wear time ≥ 20 hours per day)

**Optimal goal directed medical therapy is defined as treatment with aldosterone blockers, beta blockers, renin-angiotensin inhibitors, and sodium-glucose cotransporter-2 inhibitors.*

Continuation of Therapy
Wearable cardioverter-defibrillator devices may be **considered medically necessary** for additional 30-day intervals following the initial 90-day period when ALL the following criteria are met:

1. Device reports have been reviewed by the ordering physician and the Member's plan of care has been updated based on Member's current health status

2. Physician attestation and device report(s) have been submitted and indicate Member has been compliant with therapy since initial or last medical necessity review. Physician attestation and plan of care should indicate Member is moving towards a permanent solution (e.g., implantable cardioverter-defibrillator, cardiac transplant, ejection fraction improving and risk for sudden cardiac death is resolving, hospice/palliative care)

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Olgin et al. (2018) conducted the Vest Prevention of Early Sudden Death (VEST) trial to evaluate whether use of a wearable cardioverter-defibrillator (WCD) reduces sudden cardiac death during the high-risk 40–90-day period after myocardial infarction in patients with an ejection fraction (EF) ≤ 35%. A total of 2,302 participants were randomized 2:1 to receive WCD plus guideline-directed therapy (n = 1542) or guideline-directed therapy alone (n = 778). Participants in the WCD arm were instructed to wear the device continuously for three months, except during bathing, and study personnel were notified if daily wear time fell below 15 hours. Of the randomized cohort, 1481 participants in the WCD arm contributed to data, with 43 participants never initiating device use. Cross-over between study groups was not permitted, and early ICD implantation (<3 months) was allowed only for secondary-prevention indications. Mean follow-up duration was 84.3 ± 15.6 days, and median wear time among WCD users was 18.0 hours per day. The trial's primary endpoint, the combined ninety-day incidence of sudden death or tachyarrhythmic death, did not differ significantly between the WCD and control groups, with rates of 1.6% and 2.4%, respectively (p = 0.18). However, the secondary endpoint of all-cause mortality showed a statistically significant reduction in the WCD group (3.1%) compared with the control group (4.9%, p = 0.04). Arrhythmic death occurred in twenty-five participants in the WCD group and nineteen in the control group, with only nine WCD-group deaths occurring while the device was being worn. Twenty-nine participants wearing the WCD received shocks, including twenty appropriate and nine inappropriate therapies. Several fatalities occurred after participants aborted appropriate shocks by using the response buttons, highlighting the importance of adherence and patient education. Four adverse events were attributed to the WCD, including three hospitalizations and one death due to pulseless electrical activity upon EMS arrival. Researchers concluded that the WCD did not significantly reduce sudden cardiac death but did reduce overall mortality and demonstrated a strong dependence on patient adherence.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

Matteucci et al. (2024) completed a prospective observational study to examine the clinical use of WCDs in patients at risk for life-threatening arrhythmias in order to prevent unnecessary ICD implantation while physicians awaited clinical stabilization or recovery. A total of 41 patients met criteria for WCD placement based on de novo diagnosis of heart failure with reduced ejection fraction (HFrEF), acute coronary syndrome, myocarditis, high-risk cardiac MRI features suggestive of electrical vulnerability, or recent ICD explantation. Patients had a mean age of 59.2 years, were predominantly mail (78%), and a high prevalence of hypertension, dyslipidemia, diabetes, and smoking history. WCD wear time averaged 22.7 hours per day over a mean follow-up of 62 days, demonstrating excellent adherence. Throughout the monitoring period, no patient experienced ventricular arrhythmias requiring WCD intervention. By the end of follow-up, 15 patients still met criteria for ICD therapy, and 12 underwent ICD implantation, while two declined. The remaining patients demonstrated sufficient clinical improvement to avoid ICD placement, meaning that 69% of those initially considered at risk were able to avoid permanent device implantation. The study concluded that WCD therapy provides meaningful protection during transient periods of heightened risk and allows time to optimize medical therapy and reassess arrhythmic risk before committing to permanent ICD placement.

El-Battrawy et al. (2023) performed a retrospective study analysis of 124 patients with myocarditis and reduced left ventricular function who were prescribed a WCD. Baseline evaluation showed a median left ventricular ejection fraction (LVEF) of 30% and markedly elevated medium brain natriuretic peptide (BNP) levels of 1702 pg/mL, indicating significant myocardial injury and hemodynamic compromise. Follow-up assessments demonstrated progressive recovery, with median LVEF improving to 44% at approximately three months and further to 48% at six to twelve months. BNP levels likewise declined substantially 688 pg/mL at short-term follow-up and 188 pg/mL at long-term follow-up. Patients wore the WCD for an average of 21.0 ± 4.9 hours daily across an average of eighty days. Wear-time adherence criteria (>20 hours/day) were met by 78.2% of the cohort. Arrhythmias detected during WCD use included sustained ventricular tachycardia in 6.5% of patients, non-sustained ventricular tachycardia in 9.7%, and atrial arrhythmias in 3.1%. Only four total shocks were administered, of which three were appropriate and one inappropriate. Discontinuation of WCD therapy most commonly followed improvement in LVEF (42.4%) or clinical stabilization. ICD or LVAD implantation was pursued in 26.3% of cases, while non-compliance accounted for 4.1% of discontinuations and death for 2%. The study concluded that WCD therapy is feasible and well-tolerated in myocarditis patients and may offer meaningful arrhythmic protection during the period of myocardial healing.

Olgin et al. (2020) completed secondary analyses of VEST trial data to explore the influence of adherence on outcomes and to address effect-cause (meaning that hospitalized patients may be more likely not to wear the WCD because of being hospitalized and are at higher mortality risk due to the cause of their hospitalization) and adherence-propensity bias (patients who are more likely to wear the WCD may also be more likely to adhere to medications and other medical care or prescribed behavior). Wear-time distribution was bimodal, as 34% of participants wore the WCD for zero hours per day, while 53% wore it for twenty-two or more hours per day. Approximately 30% of participants discontinued device use within the first month, with most discontinuations occurring within the first few days after initial assignment. By the ninety-day end of follow-up, nearly 80% of participants had discontinued WCD use. Predictors of high adherence included older age, female sex, white race, lower body mass index, marital status, and experiencing cardiac arrest during the index MI. Conversely, predictors of early discontinuation included prior revascularization procedures, a history of hypertension, prior thrombolytic therapy, higher BMI, recent WCD shocks, being widowed or divorced, and an LVEF ≤25% at the index event. Importantly, most deaths in the WCD arm of the VEST trial occurred when the patient was not wearing the device. Although arrhythmic mortality did not differ significantly between trial groups, total mortality did favor WCD use, suggesting that clinical benefit is closely tied to consistent and prolonged device adherence.

WEARIT-II Registry Study
Kutyifa et al. (2015) completed the WEARIT-II Registry study, a large prospective observational investigation designed to evaluate the safety and efficacy of WCD devices in patients with ischemic cardiomyopathy, nonischemic cardiomyopathy or congenital/inherited heart disease who were considered at high risk for sudden cardiac death. A total of 2,000 patients were enrolled, including 805 with ischemic cardiomyopathy, 927 with non-ischemic cardiomyopathy, and 268 with congenital or inherited heart disease. Eligibility criteria required reduced LVEF and a clinical scenario in which ICD implantation was delayed or uncertain, such as recent myocardial infarction, recent coronary revascularization, newly diagnosed cardiomyopathy undergoing stabilization, or inherited arrhythmogenic conditions. The median baseline ejection fraction across all groups was 25%. Median duration of WCD use was 90 days, and adherence was high, with a median daily wear time of 22.5 hours that did not significantly differ among diagnostic subgroups. During the three-month WCD monitoring period, 120 episodes of sustained ventricular tachycardia or ventricular fibrillation were recorded in 41 patients. Most sustained ventricular arrhythmias did not require shock therapy because patients activated the response button, delaying treatment and allowing spontaneous arrhythmia termination. In 30 episodes associated with hemodynamic instability, the WCD delivered shock therapy, and all arrhythmias were successfully terminated with the first shock. Inappropriate WCD therapy was infrequent and occurred in only ten patients, primarily due to electrocardiographic artifact. Rates of non-sustained ventricular tachycardia and atrial tachyarrhythmias were 30 and 101 events per 100 patient-years, respectively. ICD implantation occurred in 36% of patients with non-ischemic cardiomyopathy, 42% with ischemic cardiomyopathy, and 46% with congenital or inherited heart disease. Improvement in left ventricular ejection fraction was observed in 41% of ischemic cardiomyopathy patients, 42% of non-ischemic cardiomyopathy patients, and 31% of those with congenital or inherited heart disease. Only three deaths occurred during active WCD use in the registry. The investigators concluded that WCD therapy is safe, effective, and provides valuable temporary protection during periods of elevated arrhythmic risk while permitting reassessment of long-term ICD candidacy.

Kutyifa et al. (2018) published the 12-month follow-up data for the WEARIT-II prospective trial, reporting longer-term outcomes among 1,846 of the original 2,000 participants. Over the 12-month observation period, a total of 73 deaths occurred across all patient groups, with only three of these deaths occurring during active WCD use and the remaining 70 occurring after the device had been discontinued. ICD implantation was performed in 840 patients, while 802 patients demonstrated sufficient improvement in left ventricular ejection fraction to avoid ICD placement entirely. Approximately 148 patients were lost to follow-up. Analysis of predictors of one-year mortality identified baseline renal disease, increasing age, prior syncope, and non-use of beta-blocker therapy as significant contributors to worse outcomes. Patients with ischemic and non-ischemic cardiomyopathy exhibited similarly low one-year mortality regardless of whether they ultimately received an ICD, whereas individuals with congenital or inherited heart disease experienced significantly higher mortality if they did not receive an ICD. The authors noted that strong adherence to WCD use and guideline-directed medical therapy likely contributed to the overall low early mortality rates and the high proportion of patients demonstrating left ventricular functional recovery. The long-term findings underscore the role of WCD therapy as a bridge through periods of clinical instability, enabling time for optimization of medical therapy and reassessment of ICD candidacy.

Pediatrics
Spar et al. (2018) evaluated WCD use in 455 pediatric patients under 18 years of age in the United States between 2009 and 2016. Diagnoses included cardiomyopathy, congenital heart disease, channelopathies, and prior ventricular arrhythmias or unexplained cardiac arrest. Median wear duration was thirty-three days with a median daily use of 20.6 hours. Eight patients received therapeutic shocks: six were appropriate and successfully terminated life-threatening arrhythmias, demonstrating the device's capability to deliver effective therapy when needed. Two inappropriate shocks occurred, one caused by oversensing during asystole and another due to noise artifact during sinus rhythm. Seven deaths occurred in the overall cohort, and all involved patients who were either not wearing the device at the time or had already discontinued use due to clinical deterioration or palliative care considerations. The investigators concluded that despite the lack of prospective pediatric trials, the WCD demonstrated an excellent safety profile, high adherence, and clinically meaningful arrhythmia protection in a group known for wide variation in size, developmental stage, and underlying cardiac diagnoses.

Collins et al. (2010) completed a comparative study to examine the use of WCD devices in pediatric patients relative to older adolescents and young adults aged 19 to 21 years. The study evaluated 81 pediatric patients and 103 young adults whose demographic and diagnostic profiles were broadly similar, with cardiomyopathy and primary arrhythmia representing common indications for WCD placement across both groups. Pediatric patients, however, demonstrated a notably higher prevalence of congenital heart disease compared to the older cohort, reflecting well-recognized differences in the underlying causes of sudden cardiac death risk across age groups. Median daily wear times were comparable between pediatric patients (19.7 hours/day) and young adults (19.3 hours/day). Over the study period, no pediatric patient received an appropriate therapeutic shock, limiting assessment of the device's arrhythmia-termination efficacy in this subgroup; however, one inappropriate shock occurred in a pediatric patient due to misinterpretation of sinus tachycardia. In contrast, the young adult cohort experienced several appropriate shocks, demonstrating that the device functioned successfully in terminating malignant ventricular arrhythmias in older adolescents and young adults. Reasons for WCD discontinuation included ICD implantation, planned finish of WCD therapy, improved cardiac function, cardiac transplant, non-compliance clinical deterioration, or death. Despite the lack of appropriate shock events in the pediatric group, the authors concluded that WCD therapy was feasible, safe, and well-tolerated in children. The study provided early support for the role of the WCD in pediatric arrhythmia management, paving the way for broader adoption and eventual FDA approval of pediatric use.

National and Professional Organizations

The **American Heart Association (AHA)** published an updated scientific statement on cardiovascular implantable electronic device infections and their prevention, diagnosis, and management that was endorsed by the **International Society for Cardiovascular Infectious Diseases (ISCID)** (Baddour et al. 2024). The scientific statement states that WCD devices are "a reasonable strategy when delayed reimplantation of an ICD is desired."

The **European Society of Cardiology (ESC)** published clinical practice guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (Zeppenfeld et al. 2022). The guidelines recommend that a "WCD should be considered for adult patients with a secondary prevention ICD indication, who are temporarily not candidates for ICD implantation" (class IIa, level C recommendation). The guidelines also recommend consideration of a WCD in the early phase in select patients following a myocardial infarction (class IIb, level B recommendation).

The **American Heart Association (AHA), American College of Cardiology (ACC),** and the **Heart Rhythm Society (HRS)** published joint guidelines for the management of patients with ventricular arrhythmias and for the prevention of sudden cardiac death (Al-Khatib et al. 2017). The guidelines state the following:

- Following a coronary artery bypass graft, a WCD "may play a role in patients at risk of [sudden cardiac death] in the early phase after revascularization to allow time for recovery of ventricular function."
- A WCD is an alternative to an ICD in patients with "advanced heart failure listed for heart transplant who would not otherwise qualify for ICD given the severity of illness including NYHA class IV status and/or use of inotropic infusion." The WCD device is recommended if the plan is to discharge the patient to home to await heart transplantation and does not apply to those who remain hospitalized.
- "In patients with an ICD and a history of [sudden cardiac arrest] or sustained [ventricular arrythmias] in whom removal of the ICD is required (as with infection), the [WCD] is reasonable for the prevention of [sudden cardiac death]" (class IIa, level B-NR recommendation).

- "In patients at an increased risk of [sudden cardiac death] but 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, the [WCD] may be reasonable" (class IIb, level B-NR recommendation).

SUPPLEMENTAL INFORMATION

New York Heart Association (NYHA) Functional Classification

NYHA classification has served as a vital tool for risk stratification of heart failure and for determining clinical trial eligibility and medication and device candidate eligibility (AHA 2025):

- **Class I**: Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- **Class II**: Individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III**: Individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- **Class IV**: Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of HF or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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

HCPCS (Healthcare Common Procedure Coding System)

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/08/2026 Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.

04/09/2025 Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
04/10/2024 New policy. IRO Peer Review on March 28, 2024, by a practicing, board-certified physician with a specialty in Cardiology.

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