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

Last Approval: 04/09/2025
Next Review Due By: April 2026

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 defined as "an external device capable of automatic detection and defibrillation of ventricular tachycardia and ventricular fibrillation (Chung 2023)." A WCD is composed of a fitted garment with built-in electrocardiogram sensors and defibrillation pads worn under clothing. The garment is connected to a programmable monitor, typically worn at waist level, that continuously analyzes the patient's cardiac rhythms. The device will provide an alert and/or alarm to the patient if a ventricular arrhythmia is detected. The WCD device will deliver a shock if indicated. The patient may choose to abort the shock by pressing and holding the appropriate button. According to ZOLL Medical Corporation (2024), "the entire event, from detecting a life-threatening rapid heart rhythm to automatically delivering a shock, occurs in about one minute." The WCD devices are not programmed to provide pacing in the event of bradycardia; however, the device will alert the patient that bradycardia has been detected. The ASSURE device also has a loud alarm that instructs bystanders to call emergency services and initiate cardiopulmonary resuscitation in the event asystole occurs. Information related to cardiac rhythms and shocks is stored in the monitor and can be electronically transmitted for review by the patient's care team. Each patient is provided a training session in which the patient is custom fitted for a garment and provided training on how to properly assemble, wear, and use the system, including transmitting stored data either via modem or smartphone app (DynaMed 2024; Kestra Medical Technologies 2024; ZOLL Medical Corporation 2025; Chung 2023).

A WCD device is generally indicated when there is a high-risk for sudden cardiac death and immediate implantation of an implantable cardioverter-defibrillator (ICD) is not feasible. Reasons for deferral of immediate implantation of an ICD include active infection, early post-myocardial infarction, recovery from recent surgery, lack of vascular access, limited life expectancy, and new onset systolic heart failure. Other indications for a WCD device include the need for explantation of an ICD (e.g., due to malfunction or infection) or severe heart failure and awaiting heart transplantation. A WCD device is considered a "bridge therapy" and is used for less than three months, though usage beyond the initial three months may be indicated by changes in clinical status. Patient compliance with WCD device usage is integral to successful therapy and it is recommended that patients wear the WCD device "all day," including while sleeping, with breaks for water-based activities, such as bathing and swimming (DynaMed 2024; Chung 2023; Al-Khatib et al. 2017).

Regulatory Status

There are currently two WCD devices approved by the U.S. Food and Drug Administration (FDA): the ZOLL LifeVest (P010030) and the Kestra Medical Technologies ASSURE (P200037). The LifeVest was the first WCD device FDA-approved for use on December 18, 2001 (FDA 2001), and the ASSURE received FDA approval on July 27, 2021 (FDA 2021). The LifeVest was initially approved for use in "adult patients who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator (FDA 2001)." The LifeVest (P010030 S056) received FDA-approval for use in patients < 18 years of age with a chest circumference of ≥ 26 inches (66 centimeters) and weight ≥ 18.75 kilograms (41.3 pounds) and is currently the only WCD device approved for use in pediatric patients (FDA 2015). Additional FDA supplements for each device 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) completed the Vest Prevention of Early Sudden Death (VEST) trial to assess the efficacy of WCD devices in preventing sudden cardiac death in the 40–90-day period following a myocardial infarction in patients with a low ejection fraction (defined as an ejection fraction ≤ 35% as assessed ≥ 8 hours after percutaneous coronary intervention or ≥ 48 hours following coronary artery bypass grafting). A total of 2302 participants were randomized on a 2:1 basis to WCD use with guideline-directed therapy or a control group (guideline-directed therapy alone). Approximately 1542 participants were prescribed a WCD device, and 778 participants received guideline-directed therapy. Those that were prescribed a WCD were instructed to wear the device continuously for 3 months (except while bathing). Study sites were informed if a participant wore the device for < 15 hours within a 24-hour period. According to study protocol, "crossovers from the control group to the [WCD] were not allowed, and early ICD implantation (< 3 months) was allowed only for guideline-based secondary prevention of sudden death." Follow-up occurred at 1-month with a telephone call and at 3-months with an in-person visit. The primary outcome assessed was the combined 90-day incidence of sudden death and on sudden death due to tachyarrhythmia. Secondary outcomes included 1) death from any cause, 2) hospitalization for myocardial infarction, atrial fibrillation, congestive heart failure, stroke, or sustained ventricular tachyarrhythmia, 3) WCD wear time, and 4) adverse events. Approximately 43 participants randomized to the WCD group never wore the device following randomization, leaving 1481 participants eligible for data analyses. Mean follow-up was 84.3±15.6 days with 22 participants (10 in the WCD group and 12 in the control group) lost to follow-up. Additionally, insufficient data was available to determine the cause of death for four participants (two per group). Median WCD wear time was noted to be 18.0 hours (range 3.8-22.7 hours) with a mean wear time of 14.0±9.3 hours. Results showed no significant difference between either group in terms of 90-day incidence of sudden death (WCD group = 1.6%; control group = 2.4%, p = 0.18). Total mortality for any cause for the WCD group was 3.1% (48 participants) compared to 4.9% (38 participants) for the control group (p = 0.04). Arrhythmic death occurred in 25 participants in the WCD group and 19 participants in the control group with 9 of the participants in the WCD group wearing the device at the time of death. Rehospitalization occurred in 475 participants in the WCD group compared to 253 participants in the control group with the majority of rehospitalizations in both groups occurring due to cardiovascular or trial-related causes. A total of 29 participants received at least one shock while wearing the WCD with 20 of those participants receiving an appropriate shock and 9 receiving an inappropriate shock. Of note, three participants aborted appropriate shocks by pressing the patient-response buttons and then received subsequent shocks before dying within minutes of the aborted shock. One participant aborted an appropriate shock and received an appropriate shock approximately 12 hours later but died following the shock. A total of four adverse events were reported that were related to the WCD device: three hospitalizations and one death (attributed to pulseless electrical activity on emergency medical services arrival). Researchers noted the trial did not establish a lower rate of death when compared to guideline-directed care alone.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

Matteucci et al. (2024) completed a prospective observational study to evaluate the appropriate use of wearable cardioverter-defibrillators (WCD) to avoid unnecessary implantable cardioverter-defibrillator (ICD) implantation in patients at risk for life-threatening arrhythmias. Inclusion criteria included de novo diagnosis of heart failure with reduced ejection fraction (HFrEF), acute coronary syndrome (ACS), myocarditis, positive cardiac MRI (CMR) with features predisposing to electrical instability and patients who have undergone ICD device explantation. A total of 2802 cardiology unit admissions were screened for wearable defibrillator use. A total of 41 patients received a wearable defibrillator. The average age of the patients was 59.2 years, with 78% being male. The cohort had a high prevalence of hypertension (54%), smoking (41%), dyslipidemia (66%), and diabetes (27%). WCDs were assigned based on guidelines from the Italian Association of Hospital Cardiologists and the European Society of Cardiology. Arrhythmic events, daily heart rate, physical activity, body position during the day and nighttime rest and WCD-wear-time were recorded. The average follow-up period was 62 days, with a daily wearing time of 22.7 hours. No device interventions were recorded during the follow-up period. At the end of the study, 15 patients still required an ICD, and 12 of them underwent ICD implantation, while 2 patients declined the procedure. The study concluded that the use of WCDs allowed for optimized therapy and reduced the need for ICD implantation. Inappropriate ICD implantation was avoided in 69% of the patients who received WCDs.

El-Battrawy et al. (2023) completed a retrospective study with a focus on WCD device usage in patients with myocarditis and reduced left ventricular ejection fraction or prior ventricular arrhythmia. Study data was obtained using

registry data from the multicenter registry of eight European medical centers. A total of 124 patients in the registry had a diagnosis of myocarditis with a reduced left ventricular ejection fraction and were prescribed a ZOLL LifeVest. Data from the ZOLL LifeVest Network was obtained and reviewed. Episodes of ventricular tachycardia were graded as either sustained (lasting ≥ 30 seconds) or non-sustained (lasting < 30 seconds) and WCD shocks were graded as appropriate or inappropriate. Data was collected at baseline (initial hospital stay), 3 months following prescription of the WCD device (considered short-term follow-up), and at 6-12 months (considered long-term follow-up) if available. Patients were prescribed heart failure medications appropriate to their condition (angiotensin-converting enzyme inhibitors [62.5%], angiotensin-receptor-neprilysin inhibitors [22.9%], aldosterone-antagonists [51%], or beta blockers [91.4%]). Left ventricular ejection fractions and brain natriuretic peptide levels were collected at baseline and at each follow-up period. The baseline median left ventricular ejection fraction was 30% (range 22-45%) and baseline median brain natriuretic peptide level was 1702 pg/mL (range 565-3748 pg/mL). Median left ventricular ejection fraction improved to 44% (range 30-53%) at short-term follow-up and 48% (range 39-55%) at long-term follow-up with 93/112 patients having an ejection fraction > 35% at final follow-up. Median brain natriuretic peptide levels were 688 pg/mL (range 230-1769 pg/mL) at short-term follow-up and 188 pg/mL (range 26-348 pg/mL) at long-term follow-up. The average wear time was 21.0±4.9 hours daily over a mean time period of 79.7±52.1 days with a total of 36.3% of patients in the study receiving WCD therapy for > 90 days. Therapy compliance was defined as a wear time of > 20 hours per day and the compliance rate was 78.2%. Arrhythmic events found during WCD therapy included ventricular tachycardia (n=8/124, 6.5%), non-sustained ventricular tachycardia (n=12/124, 9.7%), and atrial fibrillation or atrial flutter (n=3/98, 3.1%). A total of four shocks were delivered among all patients with three of the shocks determined to be appropriate and one shock determined to be inappropriate. Reasons for stopping WCD therapy included: 1) improved left ventricular ejection fraction (n=42/99, 42.4%), 2) no further complications with normal left ventricular ejection fraction (n=10/99, 10.1%), 3) ICD or left ventricular assist device implantation or planned implantation (n=26/99, 26.3%), 4) non-compliance with WCD therapy (n=4/99, 4.1%), 5) death (n=2/99, 2%), 6) unknown reason (n=13/99, 13.1%), and 7) decision pending (n=2/99, 2%). Researchers noted that evidence from this study suggests WCD use in patients with cardiomyopathy is feasible; however, further research is needed to determine predictors of WCD shocks in these patients due to the low number of shocks observed in this study.

Olgin et al. (2020) completed secondary as-treated and per-protocol analyses of the VEST trial data to determine if WCD compliance influenced outcomes. Initial evaluation of trial data suggested two significant biases: “effect-cause bias (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 confounding by propensity to adhere (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).” Researchers omitted events that occurred in the hospital (except in-hospital deaths that resulted from out-of-hospital cardiac arrests) to determine sensitivity to effect-cause bias and adjusted for other correlates that impacted propensity to adhere. Censoring of data during analysis occurred after the last day the WCD device was worn, either due to ICD implantation or non-compliance with therapy. Median WCD wear-time had a U-shaped distribution “with 34% [of participants] wearing the WCD for a median of 0 hours per day, and 53% wearing the WCD for a median of ≥ 22 hours.” Approximately 2.8% of participants never wore the WCD and 30% “of participants stopped wearing the WCD within 1 month of randomization, 43% within 2 months, and 80% before the end of the planned 90-day follow-up period.” Most of the participants that stopped wearing the WCD within the first month discontinued use within the first few days of prescription. Most deaths within the WCD group occurred while the participant was not wearing the device and approximately 22 out of 83 total deaths between both groups occurred while the participant was admitted to the hospital. Predictors of WCD compliance (a mean wear-time of ≥ 90% [21.6 hours] of the day) included participants that were: 1) older, 2) female, 3) white, 4) married, and 5) Polish. Additional predictors of WCD compliance included 1) having a lower body mass index and having a cardiac arrest during the index myocardial infarction. Predictors for early unplanned termination of WCD usage included 1) prior percutaneous coronary intervention, coronary artery bypass grafting, or diagnosis of hypertension, 2) receiving thrombolytics during index myocardial infarction, 3) being divorced or widowed, 4) having a higher body mass index, 5) receiving a WCD shock (appropriate or inappropriate) within the previous seven days, 6) being Asian, and 7) having an ejection fraction ≤ 25% during the index myocardial infarction. Researchers noted that although “the WCD did not statistically significantly reduce arrhythmic death…[WCD use] did show a reduction in total mortality.” Researchers noted that additional efforts should be made to emphasize device compliance.

WEARIT-II Registry Study
Kutyifa et al. (2015) completed the WEARIT-II Registry study to evaluate the safety and efficacy of WCD devices in patients diagnosed with ischemic or nonischemic cardiomyopathy or congenital/inherited heart disease. A total of 2000 patients were enrolled with 805 patients having a diagnosis of ischemic cardiomyopathy, 927 patients having a

diagnosis of nonischemic cardiomyopathy, and 268 patients having a diagnosis of congenital/inherited heart disease. Patients were eligible for inclusion if they had a low ejection fraction and a high risk for sudden cardiac death and one of the following: 1) a recent myocardial infarction, 2) following coronary revascularization, 3) new onset dilated nonischemic cardiomyopathy with high-risk for sudden cardiac death until stabilization, or 4) inherited or congenital heart disease. Patients were grouped into three cohorts: 1) patients who had ischemic cardiomyopathy with previous myocardial infarction or known coronary artery disease with a high risk for sudden cardiac death, 2) patients who had nonischemic cardiomyopathy with no known coronary artery disease, and 3) patients who had congenital/inherited heart disease. Follow-up for this portion of the registry study occurred at 3-months after initiation of WCD therapy with long-term (12-month) follow-up data to be published separately. Median baseline ejection fraction was 25% across all groups with the nonischemic cardiomyopathy group having the lowest baseline median ejection fraction (20%) and the ischemic cardiomyopathy group having the highest baseline median ejection fraction (26%). "Median duration of WCD use was 90 days and median daily use was 22.5 hours" across all groups with "no significant difference in the daily use among the subgroups." There were a total of 120 sustained ventricular tachycardia or fibrillation events reported in 41 patients. According to registry data, "most sustained [ventricular tachycardias] were not treated by the WCD because the patient used the response button to delay therapy…subsequently the [ventricular tachycardias] self-terminated." Of note, 30 of the 120 events required "WCD shock therapy owing to hemodynamic instability…all patients who required shock delivery had their…episodes successfully terminated with the first shock." The rates of nonsustained ventricular tachycardia and atrial tachyarrhythmias were 30 per 100 patient-years and 101 per 100 patient-years, respectively. Inappropriate WCD therapy only occurred in 10 patients and was attributed to electrocardiogram artifact. ICD implantation occurred "36% of patients with nonischemic cardiomyopathy, in 42% of patients with ischemic cardiomyopathy, and in 46% of patients with congenital/inherited heart disease." Ejection fraction improvement occurred in 41% of patients with ischemic cardiomyopathy, 42% of patients with nonischemic cardiomyopathy, and 31% of patients with congenital/inherited heart disease. Only three deaths occurred during WCD therapy during the first 3 months. Researchers noted that findings from this study suggest that WCD use appears to be a safe bridge therapy.

Kutyifa et al. (2018) published the 12-month (long-term) follow-up data for the WEARIT-II prospective trial with the goals of assessing 1-year all-cause mortality, analyzing 1-year survival of patients with or without sustained ventricular tachycardia or fibrillation during WCD use, and 1-year all-cause mortality by disease etiology and the decision to implant an ICD. Of the initial 2000 patients enrolled in the study, 1846 patients had follow-up data reported at 12-months. A total of 73 deaths occurred across all groups within the 12-month follow-up period with three deaths occurring during WCD use and 70 deaths occurring post-WCD use. ICD implantation occurred in 840 patients and ejection fraction improvement occurred in 802 patients. Approximately 148 patients were lost to follow-up. Study data suggested predictors of mortality included renal disease at baseline (HR 2.06), increasing age (HR 1.50 for each decade increase in age), prior syncopal episodes (HR 1.72), and non-beta-blocker use. Patients with a diagnosis of ischemic or nonischemic cardiomyopathy were noted to have an overall lower risk of 1-year mortality when compared to patients with a congenital or inherited heart disease. Patients with ischemic and nonischemic cardiomyopathy had no significant difference in mortality with or without ICD placement while patients with a history of congenital or inherited heart disease were noted to have a higher probability of mortality if they did not receive an ICD. Researchers noted that compliance with WCD use, and medical therapy may have attributed to the low mortality rates, indicating that therapy compliance provided better outcomes.

Pediatrics

Spar et al. (2018) completed a retrospective review of all pediatric patients < 18 years of age in the United States who wore a WCD device between 2009 and 2016 with the goals of determining safety, efficacy, and compliance. Study data was obtained from the device manufacturer's (ZOLL Medical Corporation) database. A total of 455 patients were identified and included in the review. Median age was 15 years (range 3-17 years). Participants were divided into two study groups: those who were prescribed a WCD due to an ICD problem requiring repair or replacement (n = 63) and those who were prescribed a WCD for any other reason (n = 392). Of those in the ICD problem group, "36 had a mechanical problem with their ICD system and 24 had an infection." In the non-ICD problem group, "167 had cardiomyopathy, 90 had congenital heart disease, 47 had channelopathies, and 36 had a cardiac arrest without another cardiac diagnosis." Approximately 231 of the patients in the non-ICD problem had either a cardiac arrest (n = 109) or a history of ventricular arrhythmia or arrhythmogenic syncope (n = 122) prior to WCD placement. WCD wear duration was noted to be shorter in the ICD problem group (26 days) compared to the non-ICD problem group (35 days) with a median wear duration of 33 days (range 1-999 days). Median wear time was 20.6 hours (range 0.3-23.8 hours) per day. A total of eight patients in the entire study population received a WCD shock with six patients receiving appropriate shocks and two receiving inappropriate shocks. Those that received appropriate shocks had successful termination of

the ventricular arrhythmia. One inappropriate shock occurred due to oversensing during asystole and one inappropriate shock occurred due to noise/artifact during sinus rhythm. A total of seven patients died with none of those patients wearing the WCD at the time of death. Of those that died, three had a congenital heart disease, three had cardiomyopathy, and one was awaiting a cardiac transplant. Reasons for WCD removal included ICD repair or placement (n = 201), improvement in ejection fraction (n = 67), heart transplant or ventricular assist device (n = 20), or for other non-medical reasons (n = 144). Researchers noted that this study demonstrated WCD safety, efficacy, compliance, and duration is adequate and similar to adults.

Collins et al. (2010) completed a comparative study to compare the use of a WCD device in pediatric patients (≤ 18 years of age) to young adults (19-21 years of age). Study data was obtained from the ZOLL LifeVest database. Approximately 81 pediatric patients were prescribed a WCD device for off-label use (FDA-approval of WCD device use in pediatric patients occurred December 2015). These patients were compared to 103 young adult patients. In respect to diagnoses at time of WCD prescriptions, a larger proportion of pediatric patients were prescribed a WCD due to congenital heart disease while both groups had a large proportion of patients prescribed a WCD due to cardiomyopathy and primary arrhythmia. Reasons for WCD prescription included ICD malfunction or infection, expected recovery of ventricular function, observation or awaiting further testing, patient or family declined ICD implantation, and pregnancy. Both groups had similar compliance with the WCD device with a median wear duration per day of 19.7 hours in the pediatric group and 19.3 hours in the young adult group. In the pediatric group, no appropriate shocks were delivered and there was only one inappropriate shock due to sinus tachycardia. In the young adult group, five appropriate shocks were delivered in two patients, and one inappropriate shock was delivered. Reasons for WCD discontinuation included ICD implantation (pediatric = 29, young adult = 30), planned finish of WCD therapy (pediatric = 13, young adult = 22), improved cardiac function (pediatric = 5, young adult = 16), cardiac transplant (pediatric = 1, young adult = 2), non-compliance (pediatric = 6, young adult = 11), clinical deterioration (pediatric = 1, young adult = 1), death (pediatric = 5, young adult = 4), and other (pediatric = 21, young adult = 17). Limited information was available regarding the deaths. Overall results indicate that WCD device usage appears to be appropriate in pediatric patients; however, researchers were unable to assess efficacy as no appropriate shocks were delivered in the pediatric group.

National and Professional Organizations

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).

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."

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 2023):

- **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

04/09/2025	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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