Wearable Cardioverter-Defibrillator Devices

Summary

External defibrillators are medical devices applied to the chest wall that can stimulate an electric current in the heart when cardiac arrest has occurred. When properly applied, free-standing external defibrillators such as automated external defibrillators (AEDs) have proven to be life-saving for individuals undergoing cardiac arrest.

Wearable cardioverter-defibrillators are defibrillators worn under clothing, usually contained within a garment such as a cloth vest, and function much in the same manner as an internal cardiac defibrillator (ICD) without requiring invasive implantation. Wearable cardioverter-defibrillators are appropriate for persons with certain life-threatening cardiac conditions to identify life-threatening ventricular tachycardia or fibrillation in a person wearing the device. The device can also apply an electric current when cardiac arrest is detected.

Wearable cardioverter-defibrillators are designed to act as a bridge to prevent sudden cardiac death in patients during periods of high risk. In general, wearable cardioverter-defibrillators are no longer needed once a patient receives definitive treatment, such as permanent ICD insertion or a cardiac transplant, or once they have recovered from a previous high-risk condition, such as a heart attack.

There are two FDA-approved wearable cardioverter-defibrillator in the United States. LifeVest® is manufactured by Zoll Medical Corporation, which received premarket approval by the Food and Drug

Administration (FDA) in 2001. The Zoll® LifeVest® Wearable Defibrillator was initially approved only for patients 18 years of age and older, but approval was extended to include children in 2015. ASSURE Wearable Cardioverter Defibrillator (WCD) System (ASSURE System), which is manufactured by Kestra Medical Technologies, Inc received premarket approval by the FDA in July 2021. It is indicated for patients 18 years of age or older who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator.

Definitions

"Wearable Cardioverter-Defibrillator" is a non-invasive external defibrillator that is used to prevent sudden cardiac death. It is worn under the clothing and is able to check the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm if needed.

"Zoll® Lifevest®" refers to the LifeVest®, a type of wearable cardioverter-defibrillator made by Zoll Medical Corporation. This term refers to models 3000, 3100, and 4000.

"Sudden Cardiac Arrest (SCA)" is a sudden, unexpected cessation of cardiac activity.

"Sudden Cardiac Death" is a sudden, unexpected death caused by loss of heart function.

"Automated External Defibrillator (AED)" is a portable device that checks the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm. It is typically applied by a bystander to a person undergoing cardiac arrest in an attempt to restore or correct a cardiac arrhythmia.

"Cardiac Arrhythmia" is an abnormal heart rhythm that may lead to cardiac arrest.

"Asystole" refers to cardiac arrest, or the cessation of cardiac (heart) activity, leading to death.

"Implantable Cardioverter-Defibrillator (ICD)" consists of a lead placed transvenously into the heart attached to a generator implanted in the chest wall. Alternatively, a lead may be placed subcutaneously (below the skin) and attached to a generator implanted in the chest wall.

"Subcutaneous Implantable Cardioverter defibrillator (SICD)" consists of a lead placed under the skin near the heart and the generator is implanted into a subcutaneous pocket or intramuscular that delivers heart-regulating electrical shocks.

Clinical Indications

The Plan considers a wearable cardioverter-defibrillator (WCD) medically necessary when the device has received FDA approval (premarket, etc.,) and ALL of the following are present:

1. The device is being ordered by a cardiologist (including electrophysiologist or heart failure specialist); *and*

2. The patient is at high risk for sudden cardiac death; *and*
3. The device can be properly fitted. For pediatric members (requesting LifeVest) the chest circumference must be at least 26 inches and body weight of 18.75 kilograms (41.3 lbs); *and*
4. The current request is for no more than 3 months for this authorization. For requests of additional extended use beyond 3 months, please see "Authorization Period & Extension Requests" below. The total duration of device usage should not exceed 6 months; *and*
5. The member meets the following criteria in 5a, 5b, 5c, OR 5d:
    a. MCG (M-157) criteria for ICD Insertion is met, but a wearable cardioverter-defibrillator is needed as an interim treatment due to one of the following:
        i. Awaiting scheduled placement of an ICD within 3-months; *or*
        ii. Placement of the ICD is precluded by a temporary condition, such as a systemic infection requiring treatment; *or*
        iii. ICD requires temporary explantation due to an infection or mechanical complication; *or*
        iv. Listed for and awaiting heart transplantation; *or*
        v. Other medical contraindications to immediate ICD placement.
    b. The member has ALL of the following:
        i. Ischemic heart disease; *and*
        ii. Documented left ventricular ejection fraction (LVEF) ≤35%; *and*
        iii. Currently within 40 days of myocardial infarction (MI) and/or within 90 days of revascularization with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG); *and*
        iv. The reevaluation of LVEF and functional class is scheduled for 1-2 months from the time of MI or for 3 months from the time of diagnosis of cardiomyopathy in the case of revascularization without MI; *and*
        v. Documentation provided from the cardiologist that the member has been counseled regarding the estimated save rate, inappropriate shock rate, and the member is highly motivated to comply with the WCD; *and*
        vi. A provider is responsible for critical data transmissions from the monitoring function of the WCD; *or*
    c. The member has ALL of the following:
        i. Non-ischemic cardiomyopathy (NICM) and class II-III HF; *and*
        ii. ≤ LVEF of 35%, and HF is newly diagnosed (<3 months guideline-directed medical therapy (GDMT) or not on optimal GDMT); *and*
        iii. The reevaluation of LVEF and functional class is scheduled for approximately 3 months from the time of initial diagnosis of NICM, and guideline-directed medical therapy is initiated with a documented plan for follow-up to up-titrate to maximum tolerated GDMT within 90 days; *and*

iv. Documentation provided from the cardiologist that the member has been counseled regarding the estimated save rate, inappropriate shock rate, and the member is highly motivated to comply with the WCD; *and*

v. A provider is responsible for critical data transmissions from the monitoring function of the WCD; *or*

d. The member had sudden cardiac death due to ventricular fibrillation, or sustained ventricular tachycardia, with LVEF more than 35%, when reversible cause is established and could be treated (electrolyte abnormalities, drug poisoning, etc.)

Pediatric Patients

Wearable cardioverter-defibrillators were recently approved by the FDA for usage in the pediatric population (e.g., LifeVest). There is currently insufficient information to evaluate the clinical efficacy and benefit of these devices in this population. The Plan understands the life-threatening nature of sudden cardiac arrest and will consider the medical necessity of wearable cardioverter-defibrillator in pediatric members on a case-by-case basis, assuming the following criteria necessary for safe fitting are met:

- Has a chest circumference of 26 inches or greater; *and*
- Weighs 18.75kg or greater; *and*
- Informed consent is provided by the parent or legal guardian.

Authorization Period & Extension Requests

When approved, authorizations are generally provided for up to a 90-day period. For bridge treatment, the initial time period begins at the date of discharge for the index event. Requests to extend the authorization period must be submitted with documentation of ≥70% compliance and continued medical necessity from the treating provider.

Experimental or Investigational / Not Medically Necessary

Wearable cardioverter-defibrillators are considered experimental, investigational, and/or not medically necessary for the following conditions, except when the specific criteria above are met:

Wearable cardioverter-defibrillators are contraindicated for use in patients with an active ICD.

A history of significant nonadherence with medical therapy and follow-up is a contraindication for wearable cardioverter-defibrillators.

The Plan considers wearable cardioverter-defibrillators experimental and investigational for all other conditions as their safety and efficacy have not been established.

The Plan considers wearable cardioverter-defibrillators experimental and investigational for members with life expectancy of <6 months.

Applicable Billing Codes

Codes considered medically necessary if clinical criteria are met:

Code	*Description*
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
93741	Electronic analysis of pacing cardioverter-defibrillator (includes interrogation, evaluation of pulse generator status, evaluation of programmable parameters at rest and during activity where applicable, using electrocardiographic recording and interpretation of recordings at rest and during exercise, analysis of event markers and device response); single chamber or wearable cardioverter-defibrillator system, without reprogramming
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
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

References

1. Adler, Arnon, Halkin, Amir, and Viskin, Sami, Wearable Cardioverter-Defibrillators. Circulation. 2013; 127: 854-860.
2. Al-Dadah, Ashraf S et al, Implantable cardioverter-defibrillators improve survival after coronary artery bypass grafting in patients with severely impaired left ventricular function. J Cardiothorac Surg. 2007; 2:6.

3. 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 Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018;138:e210–e271. doi: 10.1161/ CIR.0000000000000548.
4. Barsheshet A, Kutyifa V, Vamvouris T, et al. Study of the wearable cardioverter defibrillator in advanced heart-failure patients (SWIFT). J Cardiovasc Electrophysiol. 2017;28(7):778-784.
5. Chu, E. The Wearable Cardioverter Defibrillator: A Life (Vest) of Controversy. American College of Cardiology. Oct 15, 2020. https://www.acc.org/latest-in-cardiology/articles/2020/10/01/01/42/focus-on-ep-the-wearable-cardioverter-defibrillator-a-life-vest-of-controversy
6. Chung, Mina K. Wearable Cardioverter-Defibrillator. Up-To-Date. https://www.uptodate.com/contents/wearable-cardioverter-defibrillator?source=search_result&search=wearable%20cardio&selectedTitle=1~85 Last updated Dec 2019.Literature current through Sept 2022. .
7. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. J Am Coll Cardiol. 2010;56(3):194-203.
8. Duncker D, König T, Hohmann S, Bauersachs J, Veltmann C. Avoiding Untimely Implantable Cardioverter/Defibrillator Implantation by Intensified Heart Failure Therapy Optimization Supported by the Wearable Cardioverter/Defibrillator-The PROLONG Study. J Am Heart Assoc. 2017;6(1)
9. Epstein AE, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation. 2013;127:e283–e352.
10. Epstein AE, et al. Wearable Cardioverter-Defibrillator Use in Patients Perceived to Be at High Risk Early Post-Myocardial Infarction. J Am Coll Cardiol. 2013 Nov, 62 (21) 2000-2007.
11. Ellenbogen KA, Koneru JN, Sharma PS, et al. Benefit of the wearable cardiov implantable-cardioverter defibrillator explant. *JACC: Clinical Electrophysiology.* 2017;3(3):243-250. Doi: 10.1016/j.jacep.2016.09.002
12. Healy, Christopher A., Carrillo, Roger G., Wearable cardioverter-defibrillator for prevention of sudden cardiac death after infected implantable cardioverter-defibrillator removal: A cost-effectiveness evaluation. Heart Rhythm. 2015; 12 (7): 1565-1573.
13. Heidenreich PA, Fonarow GC, Breathett K, Jurgens CY, Pisani BA, Pozehl BJ, Spertus JA, Taylor KG, Thibodeau JT, Yancy CW, Ziaeian B. 2020 ACC/AHA clinical performance and quality measures for adults with heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. Circ Cardiovasc Qual Outcomes. 2020;13:e000099. doi:10.1161/HCQ.0000000000000099

14. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. 2004;351(24):2481-8.
15. Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, Green LA, Heidenreich PA, Ho PM, Jurgens CY, King ML, Kumbhani DJ, Pancholy S. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. Circ Cardiovasc Qual Outcomes. 2017;10:e000032. doi: 10.1161/HCQ.0000000000000032.
16. Kestra Medical Technologies. (August 2021). Kestra Medical Technologies Receives FDA Premarket Approval for ASSURE Wearable Cardioverter Defibrillator (WCD). kestramedical.com. https://kestramedical.com/resources/news/2021/08/03/fda-premarket-approval/ Accessed October 2021.
17. Klein, Helmut, Goldenberg, Ilan, Moss, Arthur, Risk stratification for implantable cardioverter defibrillator therapy: the role of the wearable cardioverter-defibrillator. Eur Heart J (2013) 34 (29): 2230-2242.
18. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). Pacing Clin Electrophysiol. 2010;33(3):353-67.
19. Kutylfa V, Moss AJ, Klein H, et al. Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients: Data From the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry). *Circulation AHA*. 2015; 132(17):1613-1619. doi:https://doi.org/10.1161/CIRCULATIONAHA.115.015677
20. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med. 2004;350(21):2151-8.
21. Kutyifa V, Moss AJ, Klein H, et al. Use of the wearable cardioverter defibrillator in high-risk cardiac patients: data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry). Circulation. 2015;132(17):1613-9.
22. Lamichhane M, Gardiner JC, Bianco NR, et al. National experience with long-term use of the wearable cardioverter defibrillator in patients with cardiomyopathy. *Journal Interventional Cardiac Electrophysiology.* 2017;48(1):11-19. doi: 10.1007/s10840-016-0194-6
23. Masri, A., Altibi, A. M., Erqou, S., Zmaili, M. A., Saleh, A., Al-Adham, R., ... & Adelstein, E. (2019). Wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death: a systematic review and meta-analysis. JACC: Clinical Electrophysiology, 5(2), 152-161.
24. Morin, Daniel P. The Role and Indications of ICD in Patients With Ischemic Cardiomyopathy Undergoing Revascularization, American College of Cardiology, Expert Analysis. 2016, Mar. http://www.acc.org/membership/person?id=0ce72283-ee15-4355-b205-4ebef6ffd9a6#sthash.YJoFXS9I.dpuf
25. Opreanu M, Wan C, Singh V, Salehi N, Ahmad J, Szymkiewicz SJ, Thakur RK. Wearable cardioverter-defibrillator as a bridge to cardiac transplantation: A national database analysis. J Heart Lung Transplant. 2015;34(10):1305. Epub 2015 May 4.

26. Olgin JE et al. Efficacy of a Wearable Cardioverter-Defibrillator after Myocardial Infarction: Results of the Vest Prevention of Early Sudden Death Trial (VEST). Abstract presented at the 67th Annual ACC Conference March 10-12, 2018. Available at http://www.abstractsonline.com/pp8/#!/4496/presentation/41742
27. Piccini JP et al. Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death A Science Advisory From the American Heart Association. Circulation 2016;133.
28. Piccini JP, 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(17):1715-27.
29. Piccini JP, Al-khatib SM, Hellkamp AS, et al. Mortality benefits from implantable cardioverter-defibrillator therapy are not restricted to patients with remote myocardial infarction: an analysis from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Heart Rhythm. 2011;8(3):393-400.
30. Poole, Jeanne E. Present Guidelines for Device Implantation: Clinical Considerations and Clinical Challenges From Pacing, Implantable Cardiac Defibrillator, and Cardiac Resynchronization Therapy. Circulation. 2014;129:383-394. http://circ.ahajournals.org/content/129/3/383
31. Poole JE, Gleva MJ, Birgersdotter-Green U, et al. A wearable cardioverter defibrillator with a low false alarm rate. J Cardiovasc Electrophysiol. 2022;1-12. doi:10.1111/jce.15417
32. Sharma, P. S., Bordachar, P., & Ellenbogen, K. A. (2017). Indications and use of the wearable cardiac defibrillator. European Heart Journal, 38(4), 258-267.
33. Singh M, Wang NC, Jain S, Voigt AH, Saba S, Adelstein EC. Utility of the Wearable Cardioverter-Defibrillator in Patients With Newly Diagnosed Cardiomyopathy: A Decade-Long Single-Center Experience. J Am Coll Cardiol. 2015;66(23):2607-2613.
34. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. 2009;361(15):1427-36.
35. US Food and Drug Administration. FDA approves wearable defibrillator for children at risk for sudden cardiac arrest. FDA news Release: December 17, 2015. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm466852.htm
36. Uyei J, Braithwaite RS. Effectiveness of wearable defibrillators: systematic review and quality of evidence. International Journal of Technology Assessment in Health Care 2014;30(2):194-202. DOI: 10.1017/S026646231400004X.
37. U.S. Food & Drug Administration. WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 LIFEVEST. PMA Number: P010030. Approval Date: 07/18/2019. accessdata.fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010030S119
38. U.S. Food & Drug Administration. LifeVest Wearable Defibrillator (Model 4000). PMA number: P010030. Approval Date: 07/05/2018. Accessdata.fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010030S100

39. U.S. Food & Drug Administration. LIFEVEST WEARABLE DEFIBRILLATOR (WCD) 3000, 4000. PMA number: P010030. Approval Date: 09/01/2016. Accessdata.fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010030S080
40. U.S. Food & Drug Administration. ASSURE Wearable Cardioverter Defibrillator System Kit (P/N 80014-001), Monitor (P/N 80008-003), Therapy Cable (P/N 80004-003), Garment Style A (P/N 80015-XXX*) and Style B (P/N 80016-XXX*), Rechargeable Battery (P/N 3322882-005), Carry Pack (3326503-003), Battery Charger (3326633-004), Tablet (P/N 80041-001) – P200037. PMA number: P200037. Approval Date: July 28, 2021. Accessdata.fda.gov. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200037
41. Wan C, Szymkiewicz SJ, Klein HU. The impact of body mass index on the wearable cardioverter defibrillator shock efficacy and patient wear time. *Am Heart J*. 2017;186:111-117. doi: 10.1016/j.ahj.2017.01.007.
42. Zoll LifeVest: https://lifevest.zoll.com/patients. Summary of Safety and Effectiveness Data (SSED), Wearable Cardioverter Defibrillator Device; Trade Name: LifeVest® Wearable Cardioverter Defibrillator. US Food and Drug Administration, December 17, 2015. http://www.accessdata.fda.gov/cdrh_docs/pdf/P010030b.pdf
43. Zishiri ET, Williams S, Cronin EM, et al. Early risk of mortality after coronary artery revascularization in patients with left ventricular dysfunction and potential role of the wearable cardioverter defibrillator. Circ Arrhythm Electrophysiol. 2013;6(1):117-28.

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