

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.074.MH
Last Review Date: 05/27/2021
Effective Date: 08/01/2021

PA.074.MH – Wearable Cardiac Defibrillator

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Wearable Cardiac Defibrillators (WCDs)** medically necessary for the following indications:

1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction
2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
3. Documented prior myocardial infarction, dilated cardiomyopathy, coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)
 - a. A measured left ventricular ejection fraction less than or equal to 35%
4. A previously implanted defibrillator now requires explanation
5. Waiting for a heart transplant, actively on the waiting list, and meets medical criteria for a heart transplant
6. Has an infectious process that precludes the initial implantation of an ICD.
7. Temporary or permanent contraindication to implantation surgery.

Note: It is expected the ordering physician will be experienced in the management of patients at risk for SCD.

For continued rental of WCD beyond initial 60 days, documentation of member's usage compliance will be required (i.e. usage log demonstrating wearing of the device for at least 22 hours per day/ greater than 90% of the time) and scheduled follow-up appointment with Cardiologist.

Patient MUST have a three month follow-up with the ordering physician. If a sustained ventricular tachyarrhythmia has occurred, or if repeat LVEF assessment continues to show LVEF \leq 35 percent, additional action needs to be taken (i.e. ICD implantation, heart transplantation, etc.). WCD is not to be a long term solution.

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Limitations - The WCD is considered investigational without proven effectiveness and not a covered benefit for members with any of the following indications:

1. A drug-refractory Class IV Congestive Heart Failure who are not candidates for heart transplantation
2. A history of psychiatric disorders that interfere with the necessary care and follow up
3. In whom a reversible triggering factor for ventricular tachycardia (VT)/ventricular fibrillation (VF) can be identified, such as ventricular tachyarrhythmias in an evolving acute myocardial infarction (MI) or electrolyte abnormalities.
4. With terminal illnesses, such as metastatic malignant cancers.
5. Less than 18 years of age.
6. With hearing or vision problems that interfere with hearing or reading the WCD messages.
7. Taking medications that would impair them from pushing the response buttons on the alarm module.
8. Unable or unwilling to wear the device continuously, except for bathing/showering.
9. Pregnant or breastfeeding.
10. Women of childbearing age that are not trying to prevent pregnancy.
11. Excessive exposure to electromagnetic interference from machinery (powerful electric motors, radio transmitters, power lines, security scanners, etc.) that can prevent the WCD from detecting arrhythmias.
12. A history of severe bradycardia or VT with need for pacing. In such cases implantable cardioverter-defibrillator (ICD) would be preferred, as initial therapy due to limitations or inability to provide pacing therapy using WCD.

Background

Sudden Cardiac Death (SCD) is defined as unanticipated death due to cardiac causes within one hour of the onset of symptoms. Ventricular fibrillation is often attributed as the leading cause of SCD. Early defibrillation enhances the patient's chance of surviving a cardiac episode due to ventricular fibrillation. Defibrillators use a series of shocks to return the heart to a normal rhythm.

Wearable Cardiac Defibrillators (WCDs) are utilized for adult patients who do not meet the criteria for an implantable cardiac defibrillator (ICD) and are at high risk for SCD. WCDs are non-invasive, the patient wears it on the outside of his/her body. WCDs are intended for temporary use (one-three months).

Codes:

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CPT Codes / HCPCS Codes / ICD-10 Codes	
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.
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 A, Halkin A, Viskin S. Wearable Cardioverter-Defibrillators. *Circulation* 2013 Feb 19;127(7):854-60. doi: 10.1161/CIRCULATIONAHA.112.146530 <http://circ.ahajournals.org/content/127/7/854.full.pdf+html>
2. Beauregard, L.M., Clinical applications of the wearable defibrillator, *Pacing Clin Electrophysiol.* 2004, January, 27:1-3. <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8159.2004.00377.x/pdf>
3. Centers for Medicare and Medicaid Services: MLN Matters-New healthcare common procedure coding system (HCPCS) code for external ventricular assist devices or any ventricular assist device (VAD) for which payment was not made under Medicare Part A, MM7888. Effective April 4, 2013. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7888.pdf>
4. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD). No. L33690 - Automatic External Defibrillators. (Contractor: NHIC, Inc.) Revision Effective Date: 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33690&ver=20&bc=CAAAAAAAAAAAAA>
5. Chung MK. The Role of the Wearable Cardioverter Defibrillator in Clinical Practice. *Cardiol Clin.* 2014 May;32(2):253-270. doi: 10.1016/j.ccl.2013.11.002. <https://www.ncbi.nlm.nih.gov/pubmed/24793801>
6. LIFEVEST: LifeVest Insurance Coverage. Medicare Wearable AED Coverage Policy. <https://lifestest.zoll.com/-/media/lifestest-zoll-com/medical-professionals/lifestest-insurance-coverage/medicare-wearable-defibrillator-coverage-policy.ashx>
7. U.S. Food and Drug Administration: Product Classification- wearable automated external defibrillator, Updated April 21, 2019.

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<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=954>

8. U.S. Food and Drug Administration: Medical devices approval; LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System – P010030; Approved December 18, 2001.
https://www.accessdata.fda.gov/cdrh_docs/pdf/p010030b.Pdf
9. Zoll: LifeVest- what is the LifeVest wearable defibrillator. © 1995-2014 ZOLL Medical Corporation. <https://www.zoll.com/news-releases/2014/08/27/lifest-vest-wearable-defibrillator-showcased-heart-failure-society-of-america-2014>

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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