South Carolina

Medicare Advantage

Policy and Procedure

Subject:	Wearable Cardioverter Defibrillators
Policy Number:	107
Department:	5B Medicare Advantage
Provision Effective Date:	
Revision Date:	

PURPOSE

The wearable cardioverter defibrillator is considered a temporary therapy for patients with a high risk for sudden cardiac death (SCD). A wearable cardioverter defibrillator is considered established when medical criteria is met.

POLICY

Coverage for a wearable cardioverter defibrillator will be provided when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met. Any device used for this procedure must have U.S. Food and Drug Administration (FDA) approval specific to the indication; otherwise it will be considered investigational.

SCOPE

Members requiring wearable cardioverter defibrillators and providers furnishing wearable cardioverter defibrillators

REFERENCE DOCUMENTS

1. Sharma PS, Bordachar P, Ellenbogen KA. Indications and use of the wearable cardiac defibrillator. European Heart Journal 2017;38(4):258-267. DOI: 10.1093/eurheartj/ehw353.
2. Al-Khatib SM, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation 2018;138(13):e272-e391. DOI: 10.1161/CIR.0000000000000549. (Reaffirmed 2020 Mar).
3. Weinstock J. Use of the wearable cardioverter defibrillator as a bridge to implantable cardioverter defibrillator. Cardiac Electrophysiology Clinics 2018;10(1):11-16. DOI: 10.1016/j.ccep.2017.11.002.
4. Chieng D, Paul V, Denman R. Current device therapies for sudden cardiac death prevention - the ICD, subcutaneous ICD and wearable ICD. Heart, Lung & Circulation 2019;28(1):65-75. DOI: 10.1016/j.hlc.2018.09.011.
5. Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57038&ver=7&lcdid=34087&stateRegion=all&contractorNumber=all&lcdStatus=all&sortBy=title&bc=AAIAAAAAIAAAAAAA&.

DEFINITIONS

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 used for adult patients who do not meet the criteria for an implantable cardiac defibrillator (ICD) and are at high risk for SCD. WCDs are noninvasive; the patient wears it on the outside of his or her body. WCDs are intended for temporary use (one to three months).

RESPONSIBILITIES

Medical director, utilization management

PROCEDURE

Medical Necessity

Wearable cardioverter-defibrillators may be medically necessary when ALL of the following are met:

- Patient is at high risk for sudden cardiac death.
- A previously implanted defibrillator now requires removal, and immediate replacement is not medically appropriate (i.e., infection, waiting for a heart transplant, actively on the waiting list and meets medical criteria for a heart transplant, as an infectious process that precludes the initial implantation of an ICD)
- It is a reassessment prior to 90 days for consideration of an extension (e.g., to determine prognosis, to determine if individual remains a candidate for life vest or to determine if individual should receive implantable cardioverter defibrillator based on prognosis).

Exceptions

- The WCD is considered investigational without proven effectiveness and not a covered benefit for members with any of the following indications:
    - A drug-refractory Class IV congestive heart failure who are not candidates for heart transplantation
    - A history of psychiatric disorders that interfere with the necessary care and follow-up
    - 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.
    - With terminal illnesses, such as metastatic malignant cancers
    - Less than 18 years of age
    - With hearing or vision problems that interfere with hearing or reading the WCD messages

  - Taking medications that would impair them from pushing the response buttons on the alarm module
  - Unable or unwilling to wear the device continuously, except for bathing/showering
  - Pregnant or breastfeeding
  - Women of childbearing age that are not trying to prevent pregnancy
  - 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
  - Need an implantable cardioverter defibrillator (ICD) or already has an ICD implanted and operating
- If a sustained ventricular tachyarrhythmia has occurred, or if repeat LVEF (Left Ventricular Ejection Fraction) assessment continues to show LVEF ≤ 35 percent, additional action needs to be taken (i.e., ICD implantation, heart transplantation, etc.). WCD is not to be a long-term solution and should only be used for one to three months until an implantable AICD can be placed.

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
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each

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APPROVAL SIGNATURES

Title	Printed Name	Signature	Date

REVISION HISTORY

Implementation Date	Description	Business Owner (Signature Required)	Approval Committee