



Clinical Review Criteria Related to Wearable Cardiac Defibrillator

I. Criteria for Approval

- A. Wearable Cardiac Defibrillators are covered when the following criteria are met:
1. The individual is at high risk for sudden cardiac death with a documented episode of Ventricular Fibrillation (VF) or Ventricular Tachycardia (VT) lasting 30 seconds or longer and meets the criteria for Implantable Cardioverter Defibrillator (ICD) placement but is not currently a candidate due to the following or refused an implantable defibrillator:
 - a. Awaiting ICD reimplantation following infection-related explantation
 - b. History of cardiac arrest due to VF or sustained, lasting 30 sec. or longer, VT (spontaneous or induced during EP study), not due to transient or irreversible cause and did not occur during the first 48 hours of an MI
 - c. Familial or inherited condition with a high risk of life threatening ventricular tachyarrhythmia, such as long QT syndrome or hypertrophic cardiomyopathy
 - d. Awaiting heart transplant
 - e. An infectious process or other temporary condition that precludes initial implant of an ICD
 - f. Documented prior MI or dilated cardiomyopathy with measured LVEF less than or equal to 35%

II. Required Documentation

- A. Clinical documentation from Cardiologist, Electrophysiologist, or Cardiothoracic Surgeon indicating diagnosis, treatment plan, intervention, timeframe

III. What is Not Covered

- A. The wearable cardioverter defibrillator (WCD) is considered experimental and investigational and not medically necessary for all other indications, including but not limited to, the following:
1. Individuals in the immediate period following an acute myocardial infarction (MI) within the last 40 days;
 2. Individuals with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation;
 3. Individuals in whom a reversible triggering factor for ventricular tachycardia/ventricular fibrillation (VT/VF) can be definitely identified, such as

ventricular tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities;

4. Individuals with terminal illnesses;
 5. Individuals with newly diagnosed nonischemic dilated cardiomyopathy
- B. Minuteman Health Insurance (MHI) considers WCDs experimental and investigational for other indications because its safety and effectiveness have not been established.

ICD 10 Codes

121.01-121.3 STEMI of left main, left anterior descending or diagonal, other coronary artery of anterior wall, left circumflex or oblique marginal, involving other sites or unspecified site

121.4 NSTEMI

142.0-142.9 Cardiomyopathy

145.81 Long QT syndrome

147.2 Paroxysmal ventricular tachycardia

149.01 Ventricular fibrillation

149.02 Ventricular flutter

Cardiac arrest

T82.110A-T82.199A Mechanical complication of automatic implantable cardiac defibrillator

T82.7XXA Infection and inflammatory reaction due to cardiac device implant and graft

HCPC Codes:

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:

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Feldman MD. Wearable Cardioverter Defibrillator for Patients at Risk for Sudden Cardiac Arrest. San Francisco, CA: California Technology Assessment Forum; 2009. Available at: http://www.ctaf.org/sites/default/files/assessments/987_file_Wearable_Cardiac_Defib_final_W.pdf (Last Accessed 11/25/15 10/14/16)

Zoll Medical Corp. What Is the LifeVest Wearable Defibrillator? 2012b. Available at: <http://www.lifevest.zoll.com/medical-professionals/lifevest-insurance-coverage> (Last Accessed 10/14/16)

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Documents.

<http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?Date=08/25/2014&DocID=L31904>

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedQtrlyComp-Newsletter-ICN909312-TextOnly.pdf>

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Summary of Changes:

02/09/2017

- III., What is Not Covered, A.: Added top line followed by sections 1-5
- Sources/Citation section: Updated Last Accessed Dates. Added website address