Quartz

Wearable Cardioverter Defibrillator

Last Revision/Review Date: November 14, 2018 **P&P # C.11.21**

A. Documentation Required:

To facilitate the authorization process referral requests must include the following:

1. The diagnosis and reported symptoms of the illness that supports the request for a wearable cardioverter defibrillator (WCD); **AND**
2. Documentation from treating providers that support the patient is a candidate for an implantable cardioverter defibrillator (ICD). Clinical notes including medical and surgical history, ejection fraction and documented arrhythmia.

B. Criteria for Medical Necessity:

1. Wearable cardioverter defibrillator devices are medically necessary in **ANY** of the following situations:
   a. When the patient has met criteria for an ICD according to their treating physician and they cannot receive an ICD due to **ANY** of the following:
      i. awaiting a heart transplant; **OR**
      ii. awaiting an ICD reimplantation following infection related removal; **OR**
      iii. systemic infectious process or other temporary medical condition which prevents implantation of the ICD.

   b. As a bridge to ICD implantation for patients immediately following MI for **EITHER** of the following criteria:
      i. spontaneous ventricular tachycardia or ventricular fibrillation within the first 48 hours post MI; **OR**
      ii. left ventricular ejection fraction (LVEF) ≤ 35%.

   c. For primary prevention, as a bridge to ICD implantation for newly diagnosed dilated cardiomyopathy with LVEF ≤ 35%.

NOTES:

A rental period of up to two months is reasonable for:

a. patients who are awaiting ICD reimplantation; **OR**
b. patients with a systemic infection or temporary condition that precludes implantation.

A rental period of up to three months is reasonable for:

a. a patient with newly diagnosed dilated cardiomyopathy; **OR**
b. for patients within 40 days following an MI, when used as a bridge to ICD; **OR**
c. for patients awaiting cardiac transplantation, with continued coverage for ongoing rental until transplantation, provided that it is determined upon review that the patient is fully compliant with use of the device.

A rental period beyond the initial three months requires documentation of continued need and will require medical director review.

C. Indications Considered Experimental, Investigational or not Medically Necessary are any other conditions than identified above including:

1. The wearable cardioverter defibrillator (WCD) is not medically necessary (e.g. the patient received an ICD or heart transplant).
2. The patient is 18 years of age or younger.
3. The patient has a vision, hearing, or developmental problem that may interfere with the perception of alarms or messages from the WCD.
4. The patient is taking medications that would interfere with his or her ability to respond to alarms or messages from the WCD.
5. The patient is pregnant, breastfeeding, or of childbearing age and is not attempting to prevent pregnancy.
6. The patient will be exposed to high levels of electromagnetic interference that may prevent the WCD from operating.
7. The patient is unable or unwilling to wear the device continuously (except when bathing).
8. The patient has a history of acute myocardial infarction within last 40 days.
9. The patient has a drug-refractory class IV congestive heart failure and therefore is not a candidate for a heart transplant.
10. The patient has a history of psychiatric disorders that interfere with necessary care and follow-up.
11. The patient has a reversible triggering factor for ventricular tachycardia or ventricular fibrillation that can be identified, such as ventricular tachyarrhythmia in evolving acute myocardial infarction of an electrolyte abnormality.
12. The patient has a terminal illness.
13. Rental of a Wearable Cardioverter Defibrillator for > 3 months when the delay in ICD placement is for a reason not related to a change in medical condition (i.e., patient indecision, employment requirements or religious beliefs)

CPT/HCPCS CODES:

K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

REFERENCES:

CMS Pub 100-03 National Coverage Determination (NCD) for Implantable Automatic Defibrillators Chapter 1; Part 1; Section 20.4.

Goldberger JJ, Cain ME, Hohnloser SH, Kadish AH, et al. American Heart Association/American College of Cardiology Foundation/Heart Rhythm Society scientific statement on noninvasive risk stratification techniques for identifying patients at risk for sudden cardiac death: a scientific statement from the American Heart Association Council on Clinical Cardiology Committee on Electrocardiography and Arrhythmias and Council on Epidemiology and Prevention. J Am Coll Cardiol 2008; 52:1179 –99.

Hayes, Winifred S. Technology at a Glance Report. LifeVest System (Asahi Kasei Corp.) Wearable Cardiac Defibrillator for Prevention of Sudden Cardiac Arrest; October 26, 2012.

National Government Services, Inc. LCD ID - L33690 Automatic External Defibrillators.

O'Gara PT, Kushner FG, Ascheim DD et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2013;127: e362–e425.

U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH) 510(k) Premarket Notification Database. Lifecor WCD® 2000 System Summary of Safety and Effectiveness. No. P010030. Rockville, MD: FDA. December 18, 2001.

WI Medicaid Topic #12697 Wearable Cardioverter Defibrillator.

Yancy CW, Jessup M, Bozkurt B, Butler J, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;128: e240–e327.

Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 Guidelines 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 and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death).