WEARABLE CARDIOVERTER-DEFIBRILLATORS

Protocol: CAR043
Effective Date: June 1, 2017

Table of Contents
COMMERCIAL & MEDICAID COVERAGE RATIONALE ............................................................... 1
MEDICARE COVERAGE RATIONALE ............................................................................................... 2
U.S.FOOD AND DRUG ADMINISTRATION (FDA) ........................................................................... 4
APPLICABLE CODES ............................................................................................................................ 5
REFERENCES ......................................................................................................................................... 5
PROTOCOL HISTORY/REVISION INFORMATION ........................................................................ 5

INSTRUCTIONS FOR USE
This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL & MEDICAID COVERAGE RATIONALE


MCG™ Care Guideline: Cardioverter-Defibrillator, Wearable ACG: A-0566 (AC)

Background
A wearable cardioverter-defibrillator consists of sensing electrodes, a continuously monitoring electrocardiogram, a microprocessor, an alarm module, and defibrillation electrodes, all incorporated into a vest worn under clothing. If ventricular fibrillation or ventricular tachycardia is detected, the alarm module warns of an impending shock, which the patient can avoid by pressing a response button. If the patient does not respond, the defibrillation electrodes release a conductive gel and deliver an electrical pulse of 50 to 280 joules, as programmed by the physician. The vest is meant to be worn continuously, except when bathing or showering. In addition to its defibrillation capabilities, the device...
acts as a loop recorder. However, the device does not provide backup pacing and is contraindicated in patients with unipolar atrial or ventricular pacing due to problems with sensing arrhythmias in those contexts.

Clinical Indications for Procedure
Wearable cardioverter-defibrillator may be indicated when ALL of the following are present:

- Patient at high risk for sudden cardiac death
- Implantable cardioverter-defibrillator not able to be placed due to 1 or more of the following
  - Infectious process or other temporary condition (eg, waiting period following cardiac event, peripartum cardiomyopathy, severe heart failure patient awaiting transplant) precludes implantable cardioverter-defibrillator placement or replacement.
  - Patient declines implantable cardioverter-defibrillator placement.
- Patient is being reassessed at 3-month intervals for implantable cardioverter-defibrillator candidacy.

Inconclusive or Non-Supportive Evidence
For myocardial infarction without severe left ventricular dysfunction, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A study of aggregate national experience with wearable cardioverter-defibrillators (3569 patients who were tracked in the manufacturer's database) showed that none of the 104 patients with recent myocardial infarction and ejection fraction greater than 35% received an appropriate shock from the wearable cardioverter-defibrillator. However, 2.9% of patients with recent myocardial infarction and ejection fraction less than or equal to 35% received appropriate wearable cardioverter-defibrillator shocks, with 80% survival.

For sudden cardiac death prevention in children, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A retrospective review of 81 pediatric patients and 103 patients age 19 to 21 years at high risk of sudden cardiac death found that while the pediatric population and young adult population were similar in terms of adherence with a wearable cardioverter-defibrillator, the study was inconclusive regarding the efficacy of the wearable defibrillator in the pediatric population.

***End of MCG Guideline

NOTES:

- Wearable Cardioverter Defibrillators are excluded for members with a chest circumference of >57 inches. The device cannot be fitted on patients whose chest circumference exceeds 57 inches (144cm) (UpToDate, 2015).
- For continued use, there must be documentation that the patient is wearing the device daily and appropriately.

MEDICARE COVERAGE RATIONALE

Medicare does not have a National Coverage Determination (NCD) for wearable cardioverter-defibrillators. Refer to the Local Coverage Determination (LCD) for Nevada for Automatic External Defibrillators (L33690) (Accessed April 2017).
Automatic External Defibrillators (L33690)
Coverage Indications, Limitations, and/or Medical Necessity

Automatic external defibrillators are covered for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described under I or II. It is expected the ordering physician be experienced in the management of beneficiaries at risk for SCD.

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I. A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the criteria (1-4), described below:
   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; or
   2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
   3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
   4. A previously implanted defibrillator now requires explantation

II. A nonwearable automatic defibrillator (E0617) is covered for beneficiaries in two circumstances. They meet either (1) both criteria A and B or (2) criteria C, described below:

   A. The beneficiary has one of the following conditions (1-8):
      1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
      2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause
      3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy
      4. Coronary artery disease with a documented prior myocardial infarction with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;
         a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
         b. The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
      5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30. Beneficiaries must not have:
         a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or,
         b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or,
         c. Had an enzyme-positive MI within past month; or,
d. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or,
e. Irreversible brain damage from preexisting cerebral disease; or,
f. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
6. Beneficiaries with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%.
7. Beneficiaries with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%
8. Beneficiaries who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure
B. Implantation surgery is contraindicated
C. A previously implanted defibrillator now requires explantation

Claims for defibrillators for other indications will be denied as **not reasonable and necessary**.

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

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**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

A wearable cardioverter-defibrillator is an automatic external defibrillator which monitors and treats a patient for ventricular defibrillation. The device is intended to be worn in home or hospital settings as prescribed and overseen by a physician.

The Zoll® Medical LifeVest® received FDA premarket approval (P010030) on December 18, 2001. The device is indicated for adult patients who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator. Additional information is available at:

On December 17, 2015, the FDA approved an expanded indication for the LifeVest to include pediatric use. The device is indicated for patients under 18 years of age who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator. Patients must have a chest circumference of 26 inches (66 centimeters) or greater and a weight of 41.3 pounds (18.75 kilograms) or greater. Additional information is available at:
APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<tr>
<th>CPT® Codes</th>
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<tr>
<td>93292</td>
<td>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</td>
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<tr>
<td>93745</td>
<td>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</td>
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CPT® is a registered trademark of the American Medical Association

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<tr>
<th>HCPCS Code</th>
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<td>K0606</td>
<td>Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
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<tr>
<td>K0607</td>
<td>Replacement battery for automated external defibrillator, garment type only, each</td>
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<tr>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
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<tr>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
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REFERENCES


PROTOCOL HISTORY/REVISION INFORMATION

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The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.