

WEARABLE CARDIOVERTER-DEFIBRILLATORS

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INSTRUCTIONS FOR USE

This Medical Policy 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 Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG^{TM} Care Guidelines, to assist us in administering health benefits. The MCG^{TM} 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.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

Some benefit documents have an explicit exclusion for batteries and battery chargers. Please see the enrollee-specific benefit document to determine coverage.

COVERAGE RATIONALE

For information regarding medical necessity review of wearable cardioverter defibrillators, when applicable, see MCG[™] Care Guidelines, 18th edition, 2014. Cardioverter-Defibrillator, Wearable. ACG: A-0566 (AC).

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
93292	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
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

CPT® is a registered trademark of the American Medical Association.

HCPCS Code	Description
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

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 in 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:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P010030. Accessed April 1, 2014.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for wearable cardioverter-defibrillators. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for <u>Automatic External Defibrillators</u>, <u>Surveillance of Implantable or Wearable Cardioverter Defibrillators (ICDs): Office, Hospital, Web, or Non-Web Based</u> and <u>Cardiac Rhythm Device Evaluation</u>. (Accessed April 2, 2014)

REFERENCES

Zoll Medical website. http://lifevest.zoll.com/. Accessed April 1, 2014.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
07/01/2014	New policy