WEARABLE CARDIOVERTER-DEFIBRILLATORS

Policy Number: 2017T0570D

Effective Date: April 1, 2017

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan 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™ 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.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

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

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, 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 policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

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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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<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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<tr>
<th>HCPCS Code</th>
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<tr>
<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>
</tr>
<tr>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
</tr>
<tr>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
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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:

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for wearable cardioverter-defibrillators. Local Coverage Determinations (LCDs) exist; see the LCDs for Automatic External Defibrillators, Cardiac Rhythm Device Evaluation and Surveillance of Implantable or Wearable Cardioverter Defibrillators (ICDs): Office, Hospital, Web, or Non-Web Based. (Accessed January 12, 2017)

REFERENCES

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<th>Action/Description</th>
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| 04/01/2017| • Reformatted and reorganized policy; transferred content to new template  
• Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 20th edition, 2016" with "MCG™ Care Guidelines, 21st edition, 2017" *(refer to 21st edition for complete details on applicable updates to the MCG™ Care Guidelines)*  
• Updated supporting information to reflect the most current FDA and CMS information  
• Archived previous policy version 2016T0570C |