BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: DURABLE MEDICAL EQUIPMENT (DME)

ORIGINAL EFFECTIVE DATE: 02/04/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Automatic External Defibrillator (AED):
A portable device designed to shock the heart back into a proper beat after sudden cardiac arrest.

The Philips HeartStart® Defibrillator is FDA-approved for home use and lawfully purchased without a prescription, effective 09/16/2004.

AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

Description: (cont.)

Wearable Cardioverter Defibrillator (WCD):
A vest with a monitor, alarm and electrodes designed to monitor and treat abnormal heart rhythms. As a cardioverter, it uses low energy electrical shocks to treat ventricular tachycardia to return to a normal rhythm. As a defibrillator, it uses high-energy electrical shocks to treat ventricular fibrillation. When an abnormal rhythm is detected, a message is displayed for the individual to press and hold two response buttons to prevent the shock treatment. If the abnormal rhythm continues and the individual loses consciousness, the response buttons are involuntarily released and the shock treatment is automatically delivered within 30 seconds. The Zoll® LifeVest® (formerly the Lifecor® WCD) is FDA-approved for adults who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator.

Criteria:

Automatic External Defibrillator (AED):

- Automatic external defibrillator for home use that is obtainable without a prescription is considered a ***benefit plan exclusion*** and ***not eligible for coverage*** as durable medical equipment under the medical benefit. This includes, *but is not limited to*, HeartStart Home Defibrillator.

Wearable Cardioverter-Defibrillator:

- **Wearable cardioverter defibrillator (e.g., LifeVest) will be reviewed by the medical director(s) and/or clinical advisor(s).**

- Wearable cardioverter defibrillator for the treatment of an individual at high risk for sudden cardiac arrest who is a candidate for an implantable cardiac defibrillator (ICD) is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Temporary contraindication (e.g., systemic infection) requires resolution prior to ICD implantation
  2. ICD has been removed and is awaiting reimplantation once contraindication is cleared

AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

Criteria: (cont.)

Wearable Cardioverter-Defibrillator: (cont.)

- Wearable cardioverter defibrillator as a bridge to ICD risk stratification and possible implantation is considered ***medically necessary*** for an individual immediately following myocardial infarction with documentation of **ANY** of the following:

  1. History of ventricular tachycardia or ventricular fibrillation after the first 48 hours
  2. Left ventricular ejection fraction ≤ 40

- Wearable cardioverter defibrillator as a bridge to ICD risk stratification and possible implantation is considered ***medically necessary*** for individuals with dilated cardiomyopathy and documentation of LVEF ≤ 35%.

- Wearable cardioverter defibrillator for the following indications as listed below when it is the sole indication for a wearable cardioverter defibrillator is considered ***not medically necessary*** and ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These indications include*:*

  - Post-coronary artery bypass graft (CABG) surgery
  - High-risk individuals awaiting heart transplant

- Wearable cardioverter defibrillator for all other indications not previously listed or if above criteria is not met is considered ***not medically necessary*** and ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

Resources:

1. 2.02.15 BCBS Association Medical Policy Reference Manual. Wearable Cardioverter-Defibrillators. Re-issue date 01/09/2014, issue date 04/29/2003.

2. American College of Cardiology. 31st Bethesda Conference Emergency Cardiac Care 1999. 2000.

3. American College of Cardiology. Position Statement Early Defibrillation. accessed 03/17/2003 2003.

4. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol.* Jul 13 2010;56(3):194-203.

5. Donahue JK. Novel strategy to reduce sudden-death risk in the healing phase after myocardial infarction. *Circulation.* 2009 Jan 6 2009;119(1):6-8.

6. Forum CTA. Wearable Cardioverter Defibrillator for Patients at Risk of Sudden Cardiac Arrest. *Blue Shield of California Foundation.* 03/11/2009.

7. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). *Pacing Clin Electrophysiol.* Mar 2010;33(3):353-367.

8. Philips. HeartStart® Home Defibrillator Product Information.

FDA 510K Summary for Philips HeartStart Home Defibrillator:

- FDA-approved indication: Designed to be used on a person in sudden cardiac arrest who is unresponsive when shaken and not breathing normally.

FDA Summary for Lifecor LifeVest WCD System:

- FDA-approved indication: For adult patients who are at risk for sudden cardiac arrest and either are not candidates for or refuse an implantable defibrillator.