BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

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| **MEDICAL COVERAGE GUIDELINES** | **ORIGINAL EFFECTIVE DATE: 02/04/14** |
| **SECTION: Durable Medical Equipment (DME)** | **LAST REVIEW DATE: 06/05/18** |
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# AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR

**Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.**

**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.**

**This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**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.**

## AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

**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.

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. The LifeVest is also approved for certain children at risk for sudden cardiac arrest but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent.

**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.

## AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

**Criteria:** (cont.)

**Wearable Cardioverter Defibrillator:**

**For automatic or subcutaneous implantable cardioverter defibrillator, see BCBSAZ Medical Coverage Guideline #O655, *"Automatic Implantable and Subcutaneous Implantable Cardioverter Defibrillators"*.**

**For biventricular pacemakers, see BCBSAZ Medical Coverage Guideline #O320, *"Biventricular Pacemaker (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure"*.**

**Requests for wearable cardioverter defibrillators will be reviewed by the medical director(s) and/or clinical advisor(s).**

- Wearable cardioverter defibrillator for the short term 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. Individual meets criteria for an implantable cardioverter defibrillator
  2. Temporary contraindication (e.g., systemic infection) requires resolution prior to ICD implantation
  3. ICD has been removed and is awaiting reimplantation once contraindication is cleared

- 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. 48 hours
  2. Left ventricular ejection fraction ≤ 35% by echocardiogram or multigated acquisition scan (MUGA)

- 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 left ventricular ejection fraction ≤ 35% by echocardiogram or multigated acquisition scan (MUGA).

## AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

**Criteria:** (cont.)

**Wearable Cardioverter Defibrillator:** (cont.)

- 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.

**Initial Approval Duration:**
90 days

## AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

**Resources:**

**Literature reviewed 06/05/18. We do not include marketing materials, poster boards and non-published literature in our review.**

**The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.**

1. 2.02.15 BCBS Association Medical Policy Reference Manual. Wearable Cardioverter Defibrillators. Re-issue date 05/04/2018, issue date 04/29/2003.

2. Adler A, Halkin A, Viskin S. Wearable cardioverter-defibrillators. *Circulation.* Feb 19 2013;127(7):854-860.

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

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

5. 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.

6. 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.

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

8. 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.

9. Philips. HeartStart® Home Defibrillator Product Information.

## AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

**Non-Discrimination Statement:**

**Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.**

**If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html**

**Multi-Language Interpreter Services:**

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

## AUTOMATIC EXTERNAL DEFIBRILLATOR AND WEARABLE CARDIOVERTER DEFIBRILLATOR (cont.)

**Multi-Language Interpreter Services:** (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
.[تماس حاصل نمایید.

Assyrian:
ܐ ܫܟܚ، ܡ ܣ ܩܛܝܩܐ ܕܡܝܢ ܫܟܚ، ܫܟܚ ܢܫܟܚܟܚ، ܟܟܬܐ ܟܟܬ Blue Cross Blue Shield of Arizona، ܫܟܚ ܢܫܟܚܟܚ، ܟܟܟܟܚ ܕܡܟܫܟܚ
ܟܫܟܐ ܟܟܟܟܚܟܐ ܟܫܟܟܟܚ ܟܟܟܟܚ. ܟܟܟܟܟ ܟܟ ܣ ܟܟܟܟܐ، ܟܟ ܟܟ ܟܟ ܟܫܟܟ ܟܟܟ 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799