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

MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/04/18
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS

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.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Description:

Total Artificial Heart (TAH):
TAH is a biventricular device that completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death. A fully bioprosthetic TAH, which is fully implanted in the pericardial sac and is electrohydraulically actuated, has been developed and tested in 2 patients but is currently experimental/investigational.

- TAH devices with FDA approval include:
  - AbioCor® Implantable Replacement Heart (Humanitarian Device Exemption)
  - CardioWest™ Total Artificial Heart

Ventricular Assist Device (VAD):
VAD is a mechanical pump that provides temporary or permanent circulatory support to a weakened heart. VAD may be used as a bridge to transplant when survival to transplantation is not expected, as permanent destination therapy when an individual with end-stage heart failure is not eligible for heart transplantation or to support circulation following open-heart surgery. VAD consists of a pump, a control system and an energy supply (battery or pneumatic). The energy supply and control system are located outside the body; the pump can be either inside or outside the body. Left VAD (LVAD) receives blood from the left ventricle and delivers it to the aorta. Right VAD (RVAD) receives blood from the right ventricle and delivers it to the pulmonary artery. Biventricular VAD (BVAD) supports both pulmonary and systemic circulation.

- VAD devices with FDA approval used for bridge to heart transplantation include:
  - HeartMate II® Left Ventricular Assist System
  - HeartMate3™ Left Ventricular Assist System
  - HeartWare® Ventricular Assist System
  - Thoratec Implantable VAD (IVAD) manufactured and distributed after October 22, 2007. The FDA recalled Thoratec IVAD, Catalog Number 10012-2555-001, serial numbers 488 or higher manufactured and distributed from October 1, 2004 through October 22, 2007

- VAD devices **with** FDA approval under the Humanitarian Device Exemption (HDE) approval process for bridge to heart transplantation include:
  - Berlin Heart® EXCOR® Pediatric VAD
  - DeBakey® VAD Child Left Ventricular Assist System

- VAD devices **with** FDA approval used in the postcardiotomy setting include:
  - CentriMag® Right Ventricular Assist Device
  - Thoratec Implantable VAD (IVAD)

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Description: (cont.)

- VAD devices **without** FDA approval include, *but are not limited to*:
  - Berlin Heart EXCOR® Adult
  - Berlin Heart INCOR®

Third Generation Continuous Flow Rotary Pump Ventricular Assist Device:
Third generation smaller LVAD continuous flow rotary pumps that have not yet received approval for marketing from the FDA include:

- DuraHeart™
- Levacor™
- VentrAssist™

Percutaneous Ventricular Assist Device (pVAD):
Percutaneous ventricular assist devices have been investigated for short-term use (6 hours or less) in individuals who require acute circulatory support. These devices consist of a catheter placed through the femoral artery and operate in one of the following ways:

1. The catheter is passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system by way of the femoral artery
2. A small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta

- pVADs **without** FDA approval include, *but are not limited to:*
  - Impella® Recover® LP 2.5 Percutaneous Cardiac Support System
  - TandemHeart® Transseptal Cannula Set-EF

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria:

Bridge to Transplantation:

- Ventricular assist devices with FDA approval are considered ***medically necessary*** as temporary therapy with documentation of **ANY** of the following:

  1. Currently listed as a candidate for heart transplantation **or** are undergoing evaluation to determine candidacy and the VAD will be a temporary alternative to human heart transplantation until a human heart donor is available
  2. Post-cardiotomy and unable to be weaned off cardiopulmonary bypass

- Implantable ventricular assist devices with FDA approval, i.e., the DeBakey VAD Child Left Ventricular Assist System is considered ***eligible for coverage*** as a bridge to heart transplantation based upon its Humanitarian Device Exemption and is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. 5 to 16 years of age
  2. Currently listed as a candidate for heart transplantation **or** is undergoing evaluation to determine candidacy
  3. End stage heart failure
  4. Body surface area (BSA) of greater than or equal to 0.7 m^2 and less than 1.5 m^2
  5. New York Heart Association (NYHA) class IV heart failure
  6. Heart failure is refractory to medical therapy

- Implantable ventricular assist devices with FDA approval, i.e., the Berlin Heart EXCOR Pediatric VAD device, is considered ***eligible for coverage*** as a bridge to heart transplantation based upon its Humanitarian Device Exemption, and is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. 16 years or younger
  2. Currently listed as heart transplantation candidate and not expected to survive until a donor heart can be obtained **OR** are undergoing evaluation to determine candidacy for heart transplantation

- Total artificial heart devices with FDA approval as a bridge to transplantation are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Biventricular failure who have no other reasonable medical or surgical options
  2. Ineligible for other univentricular or biventricular support devices
  3. Currently listed as a candidate for heart transplantation **or** are undergoing evaluation to determine candidacy for heart transplantation and not expected to survive until a donor heart can be obtained.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

Destination Therapy:

- Implantable ventricular assist devices with FDA approval are considered ***medically necessary*** as destination therapy with documentation of **ALL** of the following:

  1. Ineligible for human heart transplantation due to **ANY** of the following:

     - Age > 65 years
     - Insulin dependent diabetes mellitus with end organ damage
     - Chronic renal failure (serum creatinine > 2.5 mg/dl for ≥ 90 days)
     - Presence of other clinically significant condition (e.g., irreversible hepatic or respiratory failure)

  2. **ONE** of the following classifications of heart failure:

     - New York Heart Association (NYHA) class IV for 60 days or more
     - New York Heart Association (NYHA) class III or IV for 28 days and **ONE** of the following

       - Received 14 days or more support with an intra-aortic balloon pump, **or**
       - Dependent on IV inotropic agents, with 2 failed weaning attempts

  3. End stage heart failure with left ventricular ejection fraction of 25% or less

- Replacement of a ventricular assist device for destination therapy is considered ***medically necessary*** if above criteria are met.

Postcardiotomy Setting/Bridge to Recovery:

- Implantable ventricular assist devices with FDA approval are considered ***medically necessary*** as temporary therapy in the postcardiotomy setting in individuals who are unable to be weaned off cardiopulmonary bypass.

- Replacement of a ventricular assist device for temporary therapy is considered ***medically necessary*** if above criteria are met.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

Other Indications:

- CentriMag right ventricular assist device is considered ***eligible for coverage*** based upon its Humanitarian Device Exemption and is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Intended to provide temporary circulatory support for up to 14 days
  2. Individual is in cardiogenic shock due to acute right ventricular failure

- Replacement of implantable ventricular assist devices with FDA approval, including humanitarian device exemptions are considered ***medically necessary*** if above criteria are met.

- Ventricular assist devices for all other indications not previously listed or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  1. Insufficient evidence to support improvement outside the investigational setting.

  These devices include, *but are not limited to:*

  - Berlin Heart Excor Adult
  - Berlin Heart Incor
  - DuraHeart
  - Levacor
  - VentrAssist

- Percutaneous ventricular assist devices are considered ***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.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

Other Indications:

- Total artificial heart devices for all other indications not previously listed or if above criteria not met are considered ***experimental or investigational*** based upon:

    1. Lack of final approval from the Food and Drug Administration, and
    2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
    3. Insufficient evidence to support improvement of the net health outcome, and
    4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
    2. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 09/04/18. 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.

Resources prior to 09/04/18 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.03.11 BCBS Association Medical Policy Reference Manual. Total Artificial Hearts and Implantable Ventricular Assist Devices. Re-issue date 08/09/2018, issue date 11/30/1996.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (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 hólǫ díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. 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.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (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:
ܒ ܫܟܚ، ܡ ܡ ܩܛܝܩܐ ܕܡܝܢ ܒܗ ܫܐܠܬܐ ܥܠ Blue Cross Blue Shield of Arizona، ܫܟܚ ܫܐܠܬܐ ܒܗ ܥܠ ܡܢ ܐܢܬ ܥܒܕ ܥܡܗ ܛܒܐ ܕܐܝܬ ܠܟ ܙܟܘܬܐ ܕܬܣܥܪ ܘܕܬܫܬܡܫ ܒܠܫܢܟ ܒܠܚܘܕ ܡܕܝ ܥܠ ܚܫܒܘܢ. ܕܡܬܡܠܠ ܥܡ ܡ ܕܩܒܠܢ، ܩܪܐ ܠܡܝܢ ܕܐܝܬ ܠܗ ܫܐܠܬܐ ܘܬܫܬܡܫ ܒܡܝܢ ܕܐܝܬ ܠܟ ܙܟܘܬܐ ܕܬܣܥܪ ܘܕܬܫܬܡܫ ܒܠܫܢܟ ܒܠܚܘܕ ܡܕܝ ܥܠ ܚܫܒܘܢ. ܕܡܬܡܠܠ ܥܡ ܡ ܕܩܒܠܢ، ܩܪܐ ܠܡܝܢ 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