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.

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VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Description:

**Total Artificial Heart (TAH):**

**Syncardia Temporary TAH:**
Previously known as the CardioWest™ TAH. The Syncardia™ Temporary TAH is a pulsating biventricular device that pumps blood to both the pulmonary and systemic circulation. It is implanted into the chest after the native ventricles are excised. This device may be used as a bridge to transplant in cardiac transplant-eligible individuals at risk of imminent death from biventricular failure. It is intended for use in the hospital setting.

**AbioCor® Implantable Replacement Heart System:**
A pulsatile, electrohydraulic device for implantation in individuals with advanced heart failure that involves both pumping chambers of the heart. The natural heart is removed during the procedure. The AbioCor Replacement Heart has been investigated as treatment for individuals with severe biventricular end-stage heart disease who are not eligible for a heart transplant and who are younger than 75 years of age, require multiple inotropic support, are not treatable by left ventricular assist devices (LVAD) destination therapy and are not weanable from biventricular support if on such support.

**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.

VADs with U.S. Food and Drug Administration (FDA) approval include:
- HeartWare® Ventricular Assist System
- Thoratec® HeartMate II® LVAS
- 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 ([http://www.fda.gov/cdrh/recalls/recall-101907.html](http://www.fda.gov/cdrh/recalls/recall-101907.html))

VADs with FDA approval under the Humanitarian Device Exemption (HDE) approval process include:
- CentriMag® Right Ventricular Assist Device (RVAD)
- DeBakey® VAD Child
- Berlin Heart® EXCOR® Pediatric VAD

Berlin Heart VADs without FDA approval include:
- Excor Adult
- Incor®
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Description: (cont.)

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:
- 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
- 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 include, but are not limited to:
- Impella® Recover® LP 2.5 Percutaneous Cardiac Support System
- TandemHeart® Transseptal Cannula Set-EF

Criteria:

A. Ventricular Assist Devices as Temporary Therapy for Adults:

- 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

- CentriMag right ventricular assist device is considered **eligible for coverage** based upon its Humanitarian Device Exemption issued by the Food and Drug Administration 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 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.)

A. Ventricular Assist Devices as Temporary Therapy for Adults: (cont.)

- Ventricular assist devices that lack final approval from the Food and Drug Administration for temporary therapy or if above criteria not met 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, and
4. Insufficient evidence to support improvement outside the investigational setting.

B. Ventricular Assist Devices as Destination Therapy for Adults:

- 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 temporary therapy is considered *medically necessary* if above criteria are met.
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

B. Ventricular Assist Devices as Destination Therapy for Adults: (cont.)

- Ventricular assist devices that lack final approval from the Food and Drug Administration for destination therapy or if above criteria not met 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

C. Ventricular Assist Devices for Children:

- DeBakey VAD Child Left Ventricular Assist System is considered eligible for coverage based upon its Humanitarian Device Exemption issued by the Food and Drug Administration 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 m² and less than 1.5 m²
  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, including humanitarian device exemptions, are considered medically necessary as a bridge to heart transplantation 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
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

C. Ventricular Assist Devices for Children: (cont.)

- 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 that lack final approval from the Food and Drug Administration for use in children or if above criteria not met 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

D. Percutaneous Ventricular Assist Devices (pVADs):

- 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.)

E. Other Ventricular Assist Devices:

- The following ventricular assist devices 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
  5. 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
- VentAssist

F. Total Artificial Heart:

- 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.

- Total artificial heart devices as destination therapy 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

F. Total Artificial Heart: (cont.)

- Total artificial heart devices that lack final approval from the Food and Drug Administration or if above criteria not met 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, and
4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 10/11/16. 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. HeartWare® Ventricular Assist System Product Information. 2010.
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)


11. FDA. HeartWare Ventricular Assist System. 2012.

12. InterQual® Care Planning, Procedures. Left Ventricular Assist Device (LVAD) Insertion.


VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)


FDA Premarket Approval Database for HeartWare Ventricular Assist System:

- FDA-approved indication: For use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare system is designed for in-hospital and out-of-hospital settings including transportation via fixed wing aircraft or helicopter.

FDA Premarket Approval Database for Thoratec HeartMate II Left Ventricular Assist System LVAS:

- FDA-approved indication: For use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. It is also indicated for use in patients with New York Heart Association (NYHA) class IIIb or IV end stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and are not candidates for cardiac transplantation. The Heartmate II LVAS is intended for use both inside and outside the hospital, or for transportation of ventricular assist device patients via ground ambulance, fixed-wing aircraft, or helicopter.

FDA Humanitarian Device Exemption (HDE) for Debakey VAD Child LVAS:

- FDA-approved indication: The device is indicated for providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with body surface area of ≥ 0.7 m² and < 1.5 m²) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are listed as candidates for cardiac transplantation.
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)

FDA Humanitarian Device Exemption (HDE) for Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD):

- **FDA-approved indication:** The device is intended to provide mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients. Pediatric candidates with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

FDA Humanitarian Device Exemption (HDE) for CentriMag Right Ventricular Assist System (RVAS):

- **FDA-approved indication:** This device is intended to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure.

FDA Premarket Approval Database for Thoratec Implantable Ventricular Assist Device:

- **FDA-approved indication:** Bridge to cardiac transplantation for use in patients suffering from end-stage heart failure. The patient should meet all of the following criteria: 1) candidate for cardiac transplantation, 2) imminent risk of dying before donor heart procurement, and 3) dependence on, or incomplete response to, continue vasopressor support. Also indicated for post-cardiotomy patients who are unable to be weaned from cardiopulmonary bypass.

FDA Premarket Approval Database for Syncardia Temporary CardioWest Total Artificial Heart:

- **FDA-approved indication:** For use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. It is intended for use inside the hospital.

FDA Humanitarian Device Exemption (HDE) for AbioCor Replacement Heart:

- **FDA-approved indication:** For use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who are less than 75 years old, require multiple inotropic support, are not treatable by LVAD destination therapy and are not weanable from biventricular support if on such support.
VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)

FDA 510K Summary for Impella Recover LP 2.5 Percutaneous Cardiac Support System:

- FDA-approved indication: For partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

FDA 510K Summary for TandemHeart Transseptal Cannula Set-EF:

- FDA-approved indication: For transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (six hours or less) left ventricular bypass when connected to the TandemHeart extracorporeal blood pump which returns blood to the patient via the femoral artery or other appropriate site.
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 níilíngígíí Blue Cross Blue Shield of Arizona haadá yíí’égó bina’iddikidgo éí dodoado Háída bíí ánilyeedígíí t’aadó lo’ó yína’iddikidgo bee hazdí’áání hólo díí t’aá hazaadk’ehíí háká a’doowolgo bee haz’a doo báqí ilíiligóó. Ata’ halné’ígíí kójí bíchí’í hodlínilhí 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 thể 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 الاضرورية بلغتنا 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 tinitulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makaasap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하의 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 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。通訳とお話しされる場合、877-475-4799までお電話ください。

Farsi:

اغر شما، یا کسی که شما به آن کمک می‌دهید، سوال‌های مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian:

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

Thai: หากคุณ หรือครอบครัวของคุณมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิได้รับความช่วยเหลือและข้อมูลที่จำเป็น โดยติดต่อที่ 877-475-4799.