BlueCross BlueShield Arizona

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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 06/20/23**
SECTION: SURGERY	**LAST REVIEW DATE: 10/15/24**
	CURRENT EFFECTIVE DATE: 10/15/24
	LAST CRITERIA REVISION DATE: 10/03/23
NEXT ANNUAL REVIEW DATE: 4TH QTR 2025	**ARCHIVE DATE:**

TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES

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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

A ventricular assist device (VAD) is mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy. The VAD has also been used as a bridge to recovery in individuals with reversible conditions affecting cardiac output.

Heart Failure

Heart failure may be the consequence of a number of etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and had a reported survival rate of nearly 92% for transplants performed in 2022.The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

New York Heart Association (NYHA) Functional Classification:

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Adapted from American Heart Association

Ventricular Assist Devices

Implantable VADs are attached to the native heart, which may have enough residual capacity to withstand a device failure in the short term. In reversible heart failure conditions, the native heart may regain some function, and weaning and explanting of the mechanical support system after months of use has been described. VADs can be classified as internal or external, electrically or pneumatically powered, and pulsatile or continuous-flow. Initial devices were pulsatile, mimicking the action of a beating heart. More recent devices may use a pump, which provides continuous flow. Continuous devices may move blood in a rotary or axial flow.

Surgically implanted VADs represent a method of providing mechanical circulatory support for individuals not expected to survive until a donor heart becomes available for transplant or for whom transplantation is contraindicated or unavailable. VADs are most commonly used to support the left ventricle but right ventricular and biventricular devices may be used. The device is larger than most native hearts, and therefore the size of the individual is an important consideration; the pump may be implanted in the thorax or abdomen or remain external to the body. Inflow to the device is attached to the apex of the failed

ventricle, while outflow is attached to the corresponding great artery (aorta for the left ventricle, a pulmonary artery for the right ventricle). A small portion of the ventricular wall is removed for insertion of the outflow tube; extensive cardiotomy affecting the ventricular wall may preclude VAD use.

The intent of treatment may evolve over the course of treatment; for example, there is not necessarily a strict delineation between bridge to transplant and destination therapy, and transplant eligibility can change.

U.S. Food and Drug Administration (FDA) approved and cleared ventricular assist devices (VADs) include the following:

- Berlin Heart EXCOR Pediatric VAD
- CentriMag
- DeBakey VAD Child
- HeartMate II
- HeartMate 3 Left Ventricular Assist System

Some ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. The DeBakey VAD Child device and the Berlin Heart EXCOR Pediatric VAD have FDA approval through the humanitarian device exemption process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant (i.e., a bridge to transplant) while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support. The HeartMate3™ received expanded approval for pediatric patients with advanced refractory left ventricular heart failure in 2020.

Total Artificial Heart

The total artificial heart (TAH) is a biventricular device that completely replaces the function of the diseased heart. An internal battery requires 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.

Currently the Syncardia Temporary Total Artificial Heart is the only Total Artificial Heart available in the U.S.

Percutaneous Ventricular Assist Devices

Some circulatory assist devices are placed percutaneously (i.e., are not implanted). They may be referred to as percutaneous VADs (pVADs). Two different pVADs have been developed, the TandemHeart and the Impella device. In the TandemHeart System, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Devices in which most of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due

to the increased risk of infection and need for careful, in-hospital monitoring. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

Available percutaneous ventricular assist devices include the following:

- Impella CP
- Implella 5.5
- TandemHeart

Contraindications
Contraindications for bridge to transplant VADs and total artificial hearts include conditions that would generally exclude individuals for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders, and inadequate psychosocial support. Due to potential problems with adequate function of the VAD or total artificial heart, implantation is also contraindicated in individuals with uncorrected valvular disease.

Definitions:

Adult: Age 18 years and older.

Bridge to transplant: Use of a VAD to sustain life until a donor heart becomes available.

Destination therapy: Permanent use of the device, typically for individuals ineligible for transplantation.

Bridge to recovery: Use of a VAD results in restoration of myocardial function, sufficient that heart transplant is not needed.

Bridge to decision: Use of a VAD in an attempt to reverse secondary organ dysfunction that is a contraindication to transplant. However, these cases are often characterized as destination therapy rather than bridge to decision.

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Criteria:

Destination Therapy

- Implantable ventricular assist devices (VADs) with U.S. Food and Drug Administration (FDA) approval or clearance as destination therapy for adult individuals with end-stage heart failure is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV

  2. Left ventricular ejection fraction ≤ 25%

  3. Inotrope-dependent; OR cardiac index <2.2 liters/min/m^2, while not on inotropes and **ONE** of the following:

     - On optimal medical management, based on current heart failure practice guidelines for at least 45 of the last 60 days and are failing to respond
     - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days

Bridge to Transplantation

- Implantable VADs with FDA approval or clearance as a bridge to heart transplantation is considered ***medically necessary*** for individuals with documentation of **ALL** of the following:

  1. Individual is currently listed as a heart transplantation candidate and not expected to survive until a donor heart can be obtained or is undergoing evaluation to determine candidacy for heart transplantation

  2. Absence of contraindications

- Implantable VADs with FDA approval or clearance, including humanitarian device exemptions, as a bridge to heart transplantation in children under 18 years of age is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Child is currently listed as a heart transplantation candidate and not expected to survive until a donor heart can be obtained or is undergoing evaluation to determine candidacy for heart transplantation

  2. Absence of contraindications

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- Total artificial hearts (TAHs) with FDA approved devices as a bridge to heart transplantation is considered ***medically necessary*** for individuals with documentation of **ALL** of the following:

  1. Individual with biventricular failure who has no other reasonable medical or surgical treatment options

  2. Individual is ineligible for other univentricular or biventricular support devices

  3. Individual is currently listed as a heart transplantation candidate or is undergoing evaluation to determine candidacy for heart transplantation

  4. Individual is not expected to survive until a donor heart can be obtained

  5. Absence of contraindications

Postcardiotomy Setting/Bridge to Recovery

- Implantable VADs with FDA approval or clearance in the postcardiotomy setting in individuals who are unable to be weaned off cardiopulmonary bypass is considered ***medically necessary***.

Other Indications:

- Other applications of implantable ventricular assist devices (VADs) or total artificial hearts (TAHs) are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

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

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

  - The use of TAHs as destination therapy

TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES

- The use of non-FDA-approved or non-FDA cleared implantable VADs or TAHs is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

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

- Percutaneous VADs for all indications are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

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

Resources:

Literature reviewed 10/15/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 10/15/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

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Coding:

CPT: 33927, 33928, 33929, 33975, 33976, 33977, 33978, 33979, 33980, 33990, 33991, 33992, 33993, 33995, 33997

HCPCS: L8698, Q0478, Q0479, Q0480, Q0481, Q0482, Q0483, Q0484, Q0485, Q0486, Q0487, Q0488, Q0489, Q0490, Q0491, Q0492, Q0493, Q0494, Q0495, Q0496, Q0497, Q0498, Q0499, Q0500, Q0501, Q0502, Q0503, Q0504, Q0506, Q0507, Q0508, Q0509

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025

ORIGINAL EFFECTIVE DATE: 06/20/23
LAST REVIEW DATE: 10/15/24
CURRENT EFFECTIVE DATE: 10/15/24
LAST CRITERIA REVISION DATE: 10/03/23
ARCHIVE DATE:

TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES

History:	**Date**:	**Activity**:
Medical Policy Panel	10/15/24	Review with revisions
Medical Director (Dr. Raja, Dr. Sutanto)	10/03/24	Review with revisions
Pediatric Subspecialty Advisory Sub-Committee	08/15/24	Review with revisions
Medical Policy Panel	10/03/23	Review with revisions
Medical Policy Panel	06/20/23	Approved guideline
Medical Director (Dr. Raja)	06/15/23	Development
Medical Director (Dr. Deering, Dr. Raja)	04/12/23	Development

Policy Revisions:

10/15/24	Updated:	Description section, Resources section
10/03/23	Removed:	“Long-Term Devices” and “Short-Term Devices” from criteria section.
10/03/23	Updated:	Resources section

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TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES

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.

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA		**ORIGINAL EFFECTIVE DATE:**	**06/20/23**
SECTION: SURGERY		**LAST REVIEW DATE:**	**10/15/24**
		CURRENT EFFECTIVE DATE:	**10/15/24**
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2025		**ARCHIVE DATE:**	

TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES

Multi-Language Interpreter Services:

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:

[illegible] Blue Cross Blue Shield of Arizona، [illegible] 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