# Total Artificial Hearts and Implantable Ventricular Assist Devices

**Policy #** 00246
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*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

# When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

***Bridge to Transplantation***

Based on review of available data, the Company may consider implantable ventricular assist devices (VADs) with U.S. Food and Drug Administration (FDA) approval or clearance as a bridge to heart transplantation for patients who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation to be **eligible for coverage.****

Based on review of available data, the Company may consider implantable ventricular assist devices (VADs) with U.S. Food and Drug Administration (FDA) approval or clearance, including humanitarian device exemptions, as a bridge to heart transplantation in children 16 years old or younger who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation to be **eligible for coverage.****

Based on review of available data, the Company may consider total artificial hearts (TAHs) with U.S. Food and Drug Administration (FDA)-approved devices as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained to be **eligible for coverage.****

***Destination Therapy***
Based on review of available data, the Company may consider implantable ventricular assist devices (VADs) with U.S. Food and Drug Administration (FDA) approval or clearance as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following REMATCH Study criteria to be **eligible for coverage**.**

Patient Selection Criteria
Coverage eligibility will be considered when the following criteria are met:

- New York Heart Association class IV heart failure for ≥ 60 days, or patients in New York Heart Association class III/IV for 28 days, received ≥ 14 days' support with intra-aortic balloon pump (IABP) or dependent on IV inotropic agents, with 2 failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for one or more of the following reasons:

- Age > 65 years; or
- Insulin-dependent diabetes mellitus with end-organ damage; or
- Chronic renal failure (serum creatinine > 2.5 mg/dL for ≥ 90 days; or
- Presence of other clinically significant condition

***Post-cardiotomy Setting/Bridge to Recovery***
Based on review of available data, the Company may consider implantable ventricular assist devices (VADs) with U.S. Food and Drug Administration (FDA) approval or clearance in the postcardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass to be **eligible for coverage.****

# When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

***Other Indications***
Based on review of available data, the Company considers other applications of implantable ventricular devices or total artificial hearts (TAHs) including, but not limited to, the use of total

artificial hearts (TAHs) as destination therapy. The use of non-U.S. Food and Drug Administration (non-FDA) approved or cleared implantable ventricular assist devices (VADs) or total artificial hearts (TAHs) is considered to be **investigational.***

Based on review of available data, the Company considers percutaneous ventricular assist devices (pVADs) for all indications to be **investigational.***

# Policy Guidelines

Only 2 ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration for the pediatric population. The DeBakey VAD Child device and the Berlin Heart EXCOR Pediatric VAD have Food and Drug Administration 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 (ie, 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.

In general, candidates for bridge to transplant implantable VADs are those who are considered appropriate heart transplant candidates but who are unlikely to survive the waiting period until a human heart donor is available. Some studies have included the following hemodynamic selection criteria: either a left atrial pressure of 20 mm Hg or a cardiac index of less than 2.0 L/min/m while receiving maximal medical support. Patients with VADs are classified by the United Network for Organ Sharing as status I (ie, persons who are most ill and are considered the highest priority for transplant).

The median duration for time on the device is between 20 days and 120 days.

Contraindications for bridge to transplant VADs and total artificial hearts include conditions that would generally exclude patients 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 patients with uncorrected valvular disease.

In addition, patients must have sufficient space in the thorax and/or abdominal cavity for the device. In the case of the CardioWest Temporary Total Artificial Heart, this excludes patients with body surface areas less than 1.7 $m^2$ or who have a distance between the sternum and 10th anterior rib of less than 10 cm, as measured by computed tomography scan.

# Background/Overview

**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 has survival rates at 1, 3, and 5 years of about 91%, 85%, and 78%, respectively. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

**Treatment**

**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.

At least one VAD system developed is miniaturized and generates an artificial pulse, the HeartMate 3 Left Ventricular Assist System.

Surgically implanted VADs represent a method of providing mechanical circulatory support for patients 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 patient 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.

**Total Artificial Hearts**
Initial research into mechanical assistance for the heart focused on the TAH, 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 two patients but is currently experimental.

**Percutaneous Ventricular Assist Devices (VADs)**
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. Some circulatory assist devices are placed percutaneously (ie, are not implanted). They may be referred to aspVADs. A pVAD is placed through the femoral artery. 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. 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.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

A number of mechanical circulatory support devices have been approved or cleared for marketing by the U.S. FDA. These devices are summarized in Tables 1 and 2 and discussed in the following sections.

**Table 1. Available Mechanical Circulatory Support Devices**

| Device | Manufacturer | Approval Date | FDA Clearance | PMA, HDE, or 510(k) No. | Indication |
|---|---|---|---|---|---|
| Thoratec IVAD | Thoratec | Aug 2004 | PMA Supp | P870072 | Bridge to transplant and postcardiotomy |
| DeBakey VAD® Child | MicroMed | Feb 2004 | HDE | H030003 | Bridge to transplant in children 5-16 y |
| HeartMate II | Thoratec | Apr 2008 | PMA | P060040 | Bridge to transplant and destination |
| CentriMag | Levitronix (now Thoratec) | Oct 2008 | HDE | H070004 | Postcardiotomy |

| | | | | | |
|---|---|---|---|---|---|
| Berlin Heart EXCOR® Pediatric VAD | Berlin | Dec 2011 | HDE | H100004 | Bridge to transplant |
| HeartWare® Ventricular Assist System | HeartWare | Dec 2012 | PMA | P100047 | Bridge to transplant |
| HeartMate 3 Left Ventricular Assist System | Thoratec | Aug 2017<br><br>Oct 2018 | PMA<br><br>PMA | P160054<br><br>P160054/S008 | Bridge to transplant<br><br>Destination |

FDA: U.S. Food and Drug Administration; HDE: humanitarian device exemption; PMA: premarket approval.

**Ventricular Assist Devices**

In 1995, the Thoratec®‡ Ventricular Assist Device System (Thoratec Corp.) was approved by the FDA through the premarket approval process as a bridge to transplantation in patients with end-stage heart failure. The patient should meet all of the following criteria:

- Candidate for cardiac transplantation,
- Imminent risk of dying before donor heart procurement, and
- Dependence on, or incomplete response to, continuous vasopressor support.

In 1998, supplemental approval for this device was given for the indication of post cardiotomy patients unable to be weaned from cardiopulmonary bypass. In June 2001, supplemental approval was given for a portable external driver to permit excursions within a 2-hour travel radius of the hospital when accompanied by a trained caregiver. In 2003, supplemental approval was given to market the device as Thoratec®‡ Paracorporeal VAD. In 2004, supplemental approval was given to

a modified device to be marketed as the Thoratec®‡ Implantable VAD for the same indications. In 2008, supplemental approval was given to rescind Paracorporeal VAD use.

In August 2016, HeartWare®‡ recalled its VAD Pumps due to a design flaw that was deemed by the FDA as potentially causing serious injuries or death (class I recall). The devices affected were manufactured and distributed from March 2006 and May 2018. FDA product codes 204 and 017.
A class I recall was issued for the HeartMate 3™‡ in April 2018 affecting all manufacturing dates. FDA product code: DSQ.

**Total Artificial Heart**
In 2004, the temporary CardioWest™‡ Total Artificial Heart (SynCardia Systems) was approved by the FDA through the premarket approval process for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. This device is also intended for use inside the hospital. In 2010, the FDA approved a name change to SynCardia Temporary Total Artificial Heart. FDA product code: LOZ.

In 2006, the AbioCor®‡ Implantable Replacement Heart System (Abiomed) was approved by FDA through the humanitarian device exemption (H040006) process in severe biventricular end-stage heart disease patients who are not cardiac transplant candidates and who:

- Are younger than 75 years of age;
- Require multiple inotropic support;
- Are not treatable by left VAD destination therapy; and
- Are not weanable from biventricular support if on such support.

In addition to meeting other criteria, patients who are candidates for the AbioCor®‡ TAH must undergo a screening process to determine if their chest volume is large enough to hold the device. The device is too large for approximately 90% of women and for many men.

**Percutaneous VADs (Circulatory Assist Devices)**

**Table 2. Available Mechanical Circulatory Support Devices**

| Device | Manufacturer | Approval Date | FDA Clearance | PMA, 510(k) No. | Indication |
|---|---|---|---|---|---|
| TandemHeart® | Cardiac Assist | Sep 2005 | 510(k) | K110493 | Temporary left ventricular bypass of ≤6 h |
| Impella® Recover LP 2.5 | Abiomed | May 2008 | 510(k) | K063723 | Partial circulatory support using extracorporeal bypass control unit for ≤6 h |
| Impella 2.5 System | Abiomed | Mar 2015 | PMA | P140003 | Temporary ventricular support for ≤6 h |

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

**Comparative Efficacy of Left VAD Devices**

The mechanism of operation of left VADs has changed since their introduction. The earliest devices were pulsatile positive displacement pumps. These pumps have been largely replaced by axial continuous-flow pumps. More recently centrifugal continuous-flow pumps have also been introduced.

The evidence of the comparative efficacy of centrifugal continuous-flow vs axial continuous-flow devices consists of two randomized controlled trials of two different centrifugal continuous-flow devices. The MOMENTUM 3 trial compared HeartMate 3 centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as a bridge to transplant or destination therapy. HeartMate 3 received PMA approval as a bridge to transplant therapy in August 2017 and as destination therapy in October 2018. The destination therapy indication was based on 2-year results from MOMENTUM 3, which showed superiority of the HeartMate 3 device compared to HeartMate II on the composite primary outcome, survival at 2 years free of disabling stroke or reoperation to replace a malfunctioning device (relative risk 0.84; 95% confidence interval 0.78–0.91, p<0.001). Prevalence of stroke at 2 years was lower in the HeartMate 3 than the HeartMate 2 group (10.1% vs 19.2%; P=0.02). Measures of functional capacity and Health-Related Quality of Life did not differ between the two devices at six months. The ENDURANCE trial compared HeartWare centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as destination therapy. HeartWare is FDA-approved as a bridge to transplantation device. Both trials found the centrifugal device to be noninferior to the axial device for the primary, composite outcome including measures of survival, freedom from disabling stroke, and freedom from device failure. While there are fewer device failures with the centrifugal devices without a significant increase in disabling stroke, the HeartWare device was associated with increased risk of any stroke over a period of 2 years.

The evidence on the comparative efficacy of continuous-flow vs pulsatile-flow devices consists of a randomized controlled trial and several nonrandomized comparative studies. The randomized controlled trial reported fairly large differences in a composite outcome measure favoring the continuous-flow devices, with increases in revision and reoperation rates for the pulsatile device group being the largest factor driving the difference in outcomes. Other nonrandomized comparative studies, including a database study with large numbers of patients, have not reported important differences in clinical outcomes between devices.

# Rationale/Source

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 in those not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

**Ventricular Assist Device**

For individuals who have end-stage heart failure who receive a VAD as a bridge to transplant, the evidence includes single-arm trials and observational studies. The relevant outcomes are overall survival (OS), symptoms, functional outcomes, quality of life (QOL), and treatment-related mortality and morbidity. There is a substantial body of evidence from clinical trials and observational studies supporting implantable VADs as a bridge to transplant in patients with end-stage heart failure, possibly reducing mortality as well as improving QOL. These studies have reported that substantial numbers of patients have survived to transplant in situations in which survival would not be otherwise expected. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes a trial and multiple single-arm studies. The relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. A well-designed trial, with two years of follow-up data, has demonstrated an advantage of implantable VADs as destination therapy for patients ineligible for a heart transplant. Despite an increase in adverse events, both mortality and QOL appear to be improved for these patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Total Artificial Heart**

For individuals who have end-stage heart failure who receive a TAH as a bridge to transplant, the evidence includes case series. The relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected

population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes two case series. The relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Percutaneous Ventricular Assist Device**
For individuals with cardiogenic shock or who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. The relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD vs intra-aortic balloon pump for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies were consistent with the RCT evidence. RCTs, controlled and uncontrolled observational studies, and systematic reviews of these studies have not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cardiogenic shock refractory to intra-aortic balloon pump therapy who receive a pVAD, the evidence includes case series. The relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to intra-aortic balloon pump have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series do not provide evidence that pVADs improve mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine the effects of the technology on health outcomes.

# Supplemental Information

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2014. Vetting focused on the use of percutaneous ventricular assist devices (pVADs) under the American Heart Association and American College of Cardiology guidelines (2013) and on the use of the total artificial heart as destination therapy. All providing input supported the use of implantable VADs as destination therapy subject to the guidelines in the policy statements. Most providing input considered total artificial hearts to be investigational for destination therapy; reviewers noted that there are limited clinical trial data to support the use of total artificial hearts as destination therapy.

Most providing input considered pVADs to be investigational as a "bridge to recovery" or "bridge to decision" and for all other indications. Some reviewers noted that pVADs may improve patients' hemodynamics better than other alternatives, such as an intra-aortic balloon pump, but are associated with more complications. Some noted that, despite a lack of evidence to indicate that pVADs improve overall outcomes, there may be cases when pVADs may be considered to support intervention or treatment for a life-threatening condition.

**Practice Guidelines and Position Statements**

**American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation**

In 2020, the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation published guidelines on selected topics in mechanical circulatory support, including recommendations on the use of pVADs (Table 3). The guideline authors noted, "Compared with IABP, contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar."

**Table 3. 2020 Guidelines on Mechanical Circulatory Support**

| Recommendation | COE | LOE |
|---|---|---|
| "Percutaneous LV to aorta pumps of appropriate size should be considered for cardiogenic shock from primary LV failure." | IIA | B |

COE: class of evidence; LOE: level of evidence; LV: left ventricular.

**American College of Cardiology Foundation et al**

In 2017, the American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of American published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA. Left ventricular assist device was 1 of several treatment options recommended for patients with refractory New York Heart Association class III or IV heart failure (stage D). If symptoms were not improved after guidelines-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then left ventricular assist device would be an additional treatment option.

The 2017 update focused on changes in sections regarding biomarkers, comorbidities, and prevention of heart failure, while many of the previous recommendations remained unchanged. The American College of Cardiology Foundation and AHA (2013) released guidelines for the management of heart failure that included recommendations related to the use of MCS, including both durable and nondurable MCS devices. The guidelines categorized pVADs and extracorporeal VADs as nondurable MCS devices. Table 4 provides class IIA guidelines on MCS devices.

**Table 4. 2013 Guidelines on Mechanical Circulatory Support**

| Recommendation | COE | LOE |
|---|---|---|
| "MCS is beneficial in carefully selected patients with stage D HF*r*EF in whom definitive management (eg, cardiac transplantation) or cardiac recovery is anticipated or planned." | IIA | B |

| Recommendation | COE | LOE |
|---|---|---|
| "Nondurable MCS, including the use of percutaneous and extracorporeal ventricular assist devices (VADs), is reasonable as a "bridge to recovery" or "bridge to decision" for carefully selected patients with HF*r*EF with acute, profound hemodynamic compromise." | IIA | B |
| "Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HF*r*EF." | IIA | B |

COE: class of evidence; HF*r*EF: heart failure with reduced ejection fraction; LOE: level of evidence; MCS: mechanical circulatory support.

These 2013 guidelines also noted:
"Although optimal patient selection for MCS remains an active area of investigation, general indications for referral for MCS therapy include patients with LVEF [left ventricular ejection fraction] <25% and NYHA [New York Heart Association] class III-IV functional status despite GDMT [guideline-directed medical therapy], including, when indicated, CRT [cardiac resynchronization therapy], with either high predicted 1- to 2-year mortality (eg, as suggested by markedly reduced peak oxygen consumption and clinical prognostic scores) or dependence on continuous parenteral inotropic support. Patient selection requires a multidisciplinary team of experienced advanced HF [heart failure] and transplantation cardiologists, cardiothoracic surgeons, nurses, and ideally, social workers and palliative care clinicians."

**American Heart Association**
In 2012, the AHA published recommendations for the use of MCS. These guidelines defined nondurable MCS as intraballoon pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 5 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

**Table 5. 2012 Guidelines on MCS**

| Recommendation | COE | LOE |
|---|---|---|
| "MCS for BTT indication should be considered for transplant-eligible patients with end-stage HF who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation." | I | B |
| "Implantation of MCS in patients before the development of advanced HF … is associated with better outcomes. Therefore, early referral of HF patients is reasonable." | IIA | B |
| "MCS with a durable, implantable device for permanent therapy or DT is beneficial for patients with advanced HF, high 1-year mortality resulting from HF, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation." | I | B |
| "Elective rather than urgent implantation of DT can be beneficial when performed after optimization of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies." | IIA | C |
| "Urgent nondurable MCS is reasonable in hemodynamically compromised HF patients with end-organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile." | IIA<br>I | C<br>C |

| | | |
|---|---|---|
| "These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF." | | |
| "Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS." | IIA | B |

BTT: bridge to transplant; COE: class of evidence; DT: destination therapy; HF: heart failure; LOE: level of evidence; MCS: mechanical circulatory support.

**Heart Failure Society of America**

In 2010, the Heart Failure Society of America published guidelines on surgical approaches to the treatment of heart failure. Table 6 lists recommendations on left VADs.

**Table 6. Guidelines on Left Ventricular Assist Devices**

| **Recommendation** | **SOE** |
|---|---|
| Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant." | B |
| "Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center." | B |

| | |
|---|---|
| "Patients with refractory HF and hemodynamic instability, and/or compromised end-organ function, with relative contraindications to cardiac transplantation or permanent mechanical circulatory assistance expected to improve with time or restoration of an improved hemodynamic profile should be considered for urgent mechanical circulatory support as a 'bridge to decision.' These patients should be referred to a center with expertise in the management of patients with advanced HF." | C |

HF: heart failure; SOE: strength of evidence.

**Society for Cardiovascular Angiography and Interventions et al**
In 2015, the Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America, the Society of Thoracic Surgeons, and the American College of Cardiology published a joint clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care. This statement addressed intra-aortic balloon pumps, left atrial-to-aorta assist device (eg, TandemHeart), left ventricle-to-aorta assist devices (eg, Impella), extracorporeal membrane oxygenation, and methods of right-sided support. Specific recommendations were not made, but the statement reviews the use of MCS in patients undergoing high-risk percutaneous intervention, those with cardiogenic shock, and those with acute decompensated heart failure.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
Medicare has a national coverage determination (NCD) for artificial hearts and related devices, including VADs. The NCD, mandates coverage for VADs in the *post cardiotomy setting* as long as the following conditions are met:

- The VAD has "approval from the Food and Drug Administration (FDA)" for post-cardiotomy support.
- The VAD is "used according to the FDA-approved labeling instructions."

The NCD also mandates coverage for VADs as a *bridge to transplant* as long as the following conditions are met:

- The VAD has approval from FDA for the bridge to transplant indication.
- The VAD is "used according to the FDA-approved labeling instructions."
- "The patient is approved for heart transplantation by a Medicare-approved heart transplant center..."
- "The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD."

The NCD mandates coverage for VADs as *destination therapy* as long as the following conditions are met:

- The VAD has approval from FDA for the destination therapy indication.
- Patient selection:
    - New York Heart Association class IV end-stage left ventricular failure
    - Not candidates for heart transplantation
    - Failed to respond to optimal medical management,
    - Left ventricular ejection fraction<25%, and,
    - Demonstrated functional limitation.

"Beneficiaries receiving VADs for DT [destination therapy] must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience.... The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD."

"Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services."

The NCD mandates coverage for artificial hearts as a *bridge to transplant* or *destination therapy* when performed under coverage with evidence development when a clinical study meets the criteria outlined in the Medicare policy.

**Ongoing and Unpublished Clinical Trials**
Some currently ongoing and unpublished trials that might influence this review are listed in Table 7.

**Table 7. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| ***Ongoing*** | | | |
| NCT01633502 | Effects of Advanced Mechanical Circulatory Support in Patients With ST Segment Elevation Myocardial Infarction Complicated by Cardiogenic Shock. The Danish Cardiogenic Shock Trial | 360 | Jan 2023 |
| NCT01627821[a] | Evaluation of the Jarvik 2000 Left Ventricular Assist System With Post-Auricular Connector--Destination Therapy Study | 350 | Dec 2020 |
| NCT02468778[a] | Supporting Patients Undergoing HIgh-Risk PCI Using a High-Flow PErcutaneous Left Ventricular Support Device (SHIELD II) | 716 | Dec 2021 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT01966458[a] | A Prospective, Randomized, Controlled, Unblinded, Multi-Center Clinical Trial to Evaluate the HeartWare® Ventricular Assist Device System for Destination Therapy of Advanced Heart Failure | 494 | Aug 2020 |
| NCT02232659[a] | SynCardia 70cc Temporary Total Artificial Heart (TAH-t) for Destination Therapy (DT) | 38 | Dec 2022 |
| NCT02326402 | THEME Registry: TandemHeart Experiences and Methods | 200 | Dec 2020 |
| NCT01187368[a] | Prospective Multi-Center Randomized Study for Evaluating the EVAHEART®2 Left Ventricular Assist System: the COMPETENCE Trial | 399 | Dec 2024 |
| NCT02387112 | Early Versus Emergency Left Ventricular Assist Device Implantation in Patients Awaiting Cardiac Transplantation | 200 | Dec 2022 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT02459054[a] | SynCardia 50cc Temporary Total Artificial Heart (TAH-t) as a Bridge to Transplant | 72 | Jun 2024 |
| NCT01774656[a] | Remission From Stage D Heart Failure (RESTAGE-HF) | 40 | Dec 2017 (status unknown) |

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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# Policy History

Original Effective Date: 01/20/2010
Current Effective Date: 12/14/2020

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|---|---|
| 01/07/2010 | Medical Policy Committee approval |
| 01/20/2010 | Medical Policy Implementation Committee approval. New policy. |
| 01/06/2011 | Medical Policy Committee approval |
| 01/19/2011 | Medical Policy Implementation Committee approval. Title changed. Policy statements revised to address only implantable VADs and total artificial hearts. |
| 04/12/2012 | Medical Policy Committee approval |
| 04/25/2012 | Medical Policy Implementation Committee approval. Percutaneous VADs added to policy investigational statement and rationale. |
| 04/04/2013 | Medical Policy Committee review |
| 04/24/2013 | Medical Policy Implementation Committee approval. Added "Implantable" to the beginning of the 2nd coverage statement under Bridge to Transplant to make it consistent with the other coverage statements and the focus of the policy. Coverage statement on children amended; age range changed from 5-16 to 0-16, reflecting the approval of the BERLIN heart EXCOR device for pediatric patients aged 0-16. Clause added to coverage statement on total artificial hearts that says "…or are undergoing evaluation to determine candidacy for heart transplantation…". |
| 08/07/2014 | Medical Policy Committee review |
| 08/20/2014 | Medical Policy Implementation Committee approval. Coverage statement unchanged. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 10/29/2015 | Medical Policy Committee review |

Policy # 00246
Original Effective Date: 01/20/2010
Current Effective Date: 12/14/2020

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|---|---|
| 11/16/2015 | Medical Policy Implementation Committee approval. Coverage statement unchanged. |
| 11/03/2016 | Medical Policy Committee review |
| 11/16/2016 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 11/02/2017 | Medical Policy Committee review |
| 11/15/2017 | Medical Policy Implementation Committee approval. No change to coverage. Added new FDA information. |
| 01/01/2018 | Coding update |
| 11/08/2018 | Medical Policy Committee review |
| 11/21/2018 | Medical Policy Implementation Committee approval. No change to coverage. |
| 11/07/2019 | Medical Policy Committee review |
| 11/13/2019 | Medical Policy Implementation Committee approval. No change to coverage. |
| 11/05/2020 | Medical Policy Committee review |
| 11/11/2020 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 12/11/2020 | Coding update |

Next Scheduled Review Date: 11/2021

# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 33927, 33928, 33929, 33975, 33976, 33977, 33978, 33979, 33980, 33981, 33982, 33983, 33990, 33991, 33992, 33993, 93750<br>Codes added eff 1/1/2021: 33995, 33997 |
| HCPCS | L8698, Q0477, 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 |
| ICD-10 Diagnosis | I09.81, I11.0, I13.0, I13.2, I50.20-I50.23, I50.30-I50.33, I50.40-I50.43, I50.9 |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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