Total Artificial Hearts and Implantable Ventricular Assist Devices

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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.*

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 for adult individuals with end-stage heart failure who meet the following criteria to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered when all of the following criteria are met:

- New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV;
- Left ventricular ejection fraction ≤ 25%;
- Inotrope-dependent; OR cardiac index <2.2 liters/min/m2, while not on inotropes and also meeting 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 OR
    - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.

Bridge to Transplantation
Based on review of available data, the Company may consider implantable VADs with U.S. FDA approval or clearance as a bridge to heart transplantation for individuals 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 VADs with 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 FDA approved devices as a bridge to heart transplantation for individuals with biventricular failure who have no other reasonable medical or surgical treatment options, are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or have no other reasonable medical or surgical treatment options, are ineligible for other univentricular or biventricular support devices, 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:****

Post cardiotomy Setting/Bridge to Recovery
Based on review of available data, the Company considers implantable VADs with FDA approval or clearance in the post cardiotomy 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 assist devices (VADs) or total artificial hearts (TAHs) including, but not limited to, the use of TAHs as destination therapy to be **investigational.*** The use of non-FDA-approved or cleared implantable VADs or TAHs is considered to be **investigational.***

Based on review of available data, the Company considers Percutaneous VADs for all indications to be **investigational.***

Policy Guidelines

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.

Only 2 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 (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. Individuals 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 and 120 days.

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.

The Centers for Medicare and Medicaid Services requires that "Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. 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.

The team must include, at a minimum:

- At least 1 physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.
- At least 1 cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist."

Background/Overview

Heart Failure

According to a 2022 report from the American Heart Association and based on data collected from 2015 to 2018, roughly 6 million Americans ages 20 years or older had heart failure during that time frame. Prevalence of heart failure is projected to affect more than 8 million people 18 years of age and older by the year 2030. Between 2015 and 2018, the prevalence of heart failure was highest in non-Hispanic Black males. Based on data from the Multi-Ethnic Study of Atherosclerosis (MESA), in those without baseline cardiovascular disease, Black individuals had

the highest risk of developing heart failure (4.6 per 1000 person-years), followed by Hispanic (3.5 per 1000 person-years), White (2.4 per 1000 person-years), and Chinese individuals (1.0 per 1000 person-years). Similar findings were demonstrated in the Atherosclerosis Risk in Communities (ARIC) Community Surveillance data, in which Black men and women had the highest burden of new-onset heart failure cases and the highest-age adjusted 30-day case fatality rate in comparison to White men and women. Higher risk reflected differential prevalence of hypertension, diabetes, and low socio-economic status.

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of implantable ventricular assist devices (VADs) and artificial heart systems have been U.S. Food and Drug Administration (FDA) approved through a Humanitarian Device Exemption, 510(k), or premarket approval regulatory pathway. This section discusses currently marketed devices.

FDA maintains a list of recent device recalls at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls.

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 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.

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.

Table 1 lists the VADs currently available in the US. The HeartWare VAD System was discontinued in June 2021 due to evidence from observational studies demonstrating a higher frequency of neurological adverse events and mortality with the system compared to other commercially available left VADs.

Table 1. Available Ventricular Assist 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	Thoratec	Dec 2019	PMA	P170038	Postcardiotomy, bridge to decision
Berlin Heart EXCOR Pediatric VAD	Berlin	Jun 2017	PMA	P160035	Bridge to transplant
HeartMate 3 Left Ventricular Assist System	Thoratec	Aug 2017 Oct 2018	PMA PMA	P160054 P160054/S008	Bridge to transplant Destination

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

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 (Syncardia Systems) is the only Total Artificial Heart available in the US (Table 2). The AbioCor Total Artificial Heart was FDA approved under the Humanitarian Device Exemption program in 2006, but is no longer being marketed or in development.

Table 2. Available Total Artificial Heart

Device	Manufacturer	Approval Date	FDA Clearance	PMA No.	Indication

SynCardia Temporary Total Artificial Heart (Formerly CardioWest Total Artificial Heart and Jarvik Total Artificial Heart)	SynCardia Systems	2004	510(k)	P030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

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

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 (Table 3). 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.

Table 3. Available Percutaneous Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, 510(k) No.	Indication
TandemHeart	Cardiac Assist	Sep 2011	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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 patients with reversible conditions affecting cardiac output.

Summary of Evidence

Ventricular Assist Device

For individuals who have end-stage heart failure who receive a ventricular assist device (VAD) as a bridge to transplant, the evidence includes a randomized controlled trial (RCT), single-arm trials, and observational studies. 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 an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes RCTs and multiple single-arm studies. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. A well-designed trial with 2 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. A more recent trial comparing VADs has broader inclusion criteria and supports that criteria move away from use of transplant ineligibility, as treatment may evolve over the course of treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Total Artificial Heart

For individuals who have end-stage heart failure who receive a total artificial heart (TAH) as a bridge to transplant, the evidence includes case series. 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 an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. 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 that the technology results in an improvement in the net health outcome.

Percutaneous Ventricular Assist Device

For individuals with cardiogenic shock who receive a percutaneous VAD (pVAD), the evidence includes RCTs, observational studies, and a systematic review. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD versus intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies and a long-term follow-up study were consistent with the RCT evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes RCTs, observational studies, and systematic reviews of these trials. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Randomized controlled trials, 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. Additionally, 2 nonrandomized studies have compared ventricular tachycardia (VT) ablation with pVAD or IABP. Both studies demonstrated that patients who had pVAD support spent less time in unstable VT than patients without pVAD support. However, the current evidence does not support conclusions about the use of pVAD for VT ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cardiogenic shock refractory to IABP therapy who receive a pVAD, the evidence includes case series. 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 IABP 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 that the technology results in an improvement in the net health outcome.

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.

2014 Input

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

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association for Thoracic Surgery et al

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 4). The guideline authors noted, "Compared with IABP [intraaortic balloon pump], contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar."

Table 4. 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 guideline-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then a 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 mechanical circulatory support (MCS), including both durable and nondurable MCS devices. The guidelines categorized pVADs and extracorporeal ventricular assist devices (VADs) as nondurable MCS devices. Since the 2017 update, these guidelines have been updated regularly, with the most recent update occurring in 2022. Table 5 provides recommendations on MCS devices from the most recently updated guideline iteration.

Table 5. AHA/ACC/HFSA Guidelines on Mechanical Circulatory Support

Recommendation	COE[a]	LOE[b]
"In select patients with advanced HFrEF with NYHA class IV symptoms who are deemed to be dependent on continuous intravenous inotropes or temporary MCS, durable LVAD implantation is effective to improve functional status, QOL, and survival."	I	A
"In select patients with advanced HFrEF who have NYHA class IV symptoms despite GDMT, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality."	IIA	B-R
"In patients with advanced HFrEF and hemodynamic compromise and shock, temporary MCS, including percutaneous and extracorporeal ventricular assist devices, are reasonable as a 'bridge to recovery' or 'bridge to decision'"	IIA	B-NR

ACC: American College of Cardiology; AHA: American Heart Association; COE: class of evidence; GDMT: guideline-directed medical therapy; HF*r*EF: heart failure with reduced ejection fraction; HFSA: Heart Failure Society of America; LOE: level of evidence; LVAD: left ventricular assist device; MCS: mechanical circulatory support; NYHA: New York Heart Association; QOL: quality of life; RCT: randomized controlled trial.
[a]I: Strong; IIa: Moderate.
[b]A: high quality evidence from more than 1 RCT; B-R: Moderate-quality evidence from 1 or more RCTs; B-NR: Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies.

American Heart Association

In 2012, the AHA published recommendations for the use of MCS. These guidelines defined nondurable MCS as IABPs, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 6 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 6. 2012 Guidelines on Mechanical Circulatory Support

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." "These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF."	IIA I	C C
"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.

International Society for Heart and Lung Transplantation

The International Society for Heart and Lung Transplantation and the Heart Failure Society of America released a guideline on acute MCS in 2023. The guideline focuses on timing, patient and device selection of acute MCS, and periprocedural and postprocedural care for cardiogenic and pulmonary shock. They provide specific recommendations depending on which MCS device is chosen. Table 7 summarizes relevant recommendations for timing of acute MCS made in the guidelines. Additional recommendations related to specific devices is related to procedural considerations.

Table 7. ISHLT/HFSA Guideline on Acute MCS

Recommendation	COR	LOE
"Acute MCS should be initiated as soon as possible in patients with CS who fail to stabilize or continue to deteriorate despite initial interventions."	I	B
"The use of acute MCS should be considered in patients with multiorgan failure to allow successful optimization of clinical status and neurologic assessment before placement of durable MCS or organ transplantation."	II	C

COR: class of recommendation; CS: cardiogenic shock; HFSA: Heart Failure Society of America; ISHLT: International Society for Heart and Lung Transplantation; LOE: level of evidence; MCS: mechanical circulatory support

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 MCS devices in cardiovascular care. This statement addressed IABPs, 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 VADs. The NCD mandates coverage for VADs for the following indications:

- For support of blood circulation in the post cardiotomy setting, defined as the period following open-heart surgery.
    - If the VAD has U.S. Food and Drug Administration (FDA) approval for that purpose and are used according to the FDA-labeled indication
- For short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for patients who meet the following criteria:
    - Have New York Heart Association (NYHA) Class IV heart failure; and
    - Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
    - Are inotrope dependent
      OR
      have a cardiac index < 2.2 L/min/m2, while not on inotropes, and also meet 1 of the following:
        - Are on optimal medical management, based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; OR
        - Have advanced heart failure for at least 14 days and are dependent on an IABP or similar temporary mechanical circulatory support for at least 7 days.

"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."

Effective December 1, 2020, Artificial Hearts has been removed from the NCD Manual. Coverage determinations for artificial hearts and related devices shall be made by the Medicare Administrative Contractors.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 8.

Table 8. 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 2024
NCT01627821[a]	Evaluation of the Jarvik 2000 Left Ventricular Assist System With Post-Auricular Connector--Destination Therapy Study	350	Dec 2023
NCT02232659[a]	SynCardia 70cc Temporary Total Artificial Heart (TAH-t) for Destination Therapy (DT)	38	May 2022
NCT02326402[a]	THEME Registry: TandemHeart Experiences and Methods	450	Jun 2023
NCT01187368[a]	Prospective Multi-Center Randomized Study for Evaluating the EVAHEART®2 Left Ventricular Assist System: the COMPETENCE Trial	399	Mar 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
NCT04768322	Left Ventricular Assist Device (LVAD) Versus Guideline Recommended Medical Therapy in Ambulatory Advanced Heart Failure Patients (GDMT)	92	Feb 2027

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

References

1. Tsao CW, Aday AW, Almarzooq ZI, et al. Heart Disease and Stroke Statistics-2022 Update: A Report From the American Heart Association. Circulation. Feb 22 2022; 145(8): e153-e639. PMID 35078371
2. Lewsey SC, Breathett K. Racial and ethnic disparities in heart failure: current state and future directions. Curr Opin Cardiol. May 01 2021; 36(3): 320-328. PMID 33741769
3. Organ Procurement and Transplantation Network. Heart Kaplan-Meier Patient Survival Rates For Transplants Performed : 2008 - 2015. 2018; https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.
4. TEC Assessment Program. Ventricular assist devices in bridging to heart transplantation. 1996;Volume 11;Tab 26.
5. Goldstein DJ, Oz MC, Rose EA. Implantable left ventricular assist devices. N Engl J Med. Nov 19 1998; 339(21): 1522-33. PMID 9819452
6. Mehra MR, Uriel N, Naka Y, et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. N Engl J Med. Apr 25 2019; 380(17): 1618-1627. PMID 30883052
7. Colombo PC, Mehra MR, Goldstein DJ, et al. Comprehensive Analysis of Stroke in the Long-Term Cohort of the MOMENTUM 3 Study. Circulation. Jan 08 2019; 139(2): 155-168. PMID 30586698
8. Cowger JA, Naka Y, Aaronson KD, et al. Quality of life and functional capacity outcomes in the MOMENTUM 3 trial at 6 months: A call for new metrics for left ventricular assist device patients. J Heart Lung Transplant. Jan 2018; 37(1): 15-24. PMID 29153637
9. Goldstein DJ, Naka Y, Horstmanshof D, et al. Association of Clinical Outcomes With Left Ventricular Assist Device Use by Bridge to Transplant or Destination Therapy Intent: The

Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM 3) Randomized Clinical Trial. JAMA Cardiol. Apr 01 2020; 5(4): 411-419. PMID 31939996
10. Slaughter MS, Pagani FD, McGee EC, et al. HeartWare ventricular assist system for bridge to transplant: combined results of the bridge to transplant and continued access protocol trial. J Heart Lung Transplant. Jul 2013; 32(7): 675-83. PMID 23796152
11. Strueber M, O'Driscoll G, Jansz P, et al. Multicenter evaluation of an intrapericardial left ventricular assist system. J Am Coll Cardiol. Mar 22 2011; 57(12): 1375-82. PMID 21414534
12. Aaronson KD, Eppinger MJ, Dyke DB, et al. Left ventricular assist device therapy improves utilization of donor hearts. J Am Coll Cardiol. Apr 17 2002; 39(8): 1247-54. PMID 11955839
13. Frazier OH, Gemmato C, Myers TJ, et al. Initial clinical experience with the HeartMate II axial-flow left ventricular assist device. Tex Heart Inst J. 2007; 34(3): 275-81. PMID 17948075
14. John R, Kamdar F, Liao K, et al. Improved survival and decreasing incidence of adverse events with the HeartMate II left ventricular assist device as bridge-to-transplant therapy. Ann Thorac Surg. Oct 2008; 86(4): 1227-34; discussion 1234-5. PMID 18805167
15. Miller LW, Pagani FD, Russell SD, et al. Use of a continuous-flow device in patients awaiting heart transplantation. N Engl J Med. Aug 30 2007; 357(9): 885-96. PMID 17761592
16. Patel ND, Weiss ES, Schaffer J, et al. Right heart dysfunction after left ventricular assist device implantation: a comparison of the pulsatile HeartMate I and axial-flow HeartMate II devices. Ann Thorac Surg. Sep 2008; 86(3): 832-40; discussion 832-40. PMID 18721570
17. Strüber M, Sander K, Lahpor J, et al. HeartMate II left ventricular assist device; early European experience. Eur J Cardiothorac Surg. Aug 2008; 34(2): 289-94. PMID 18571932
18. Kirklin JK, Naftel DC, Stevenson LW, et al. INTERMACS database for durable devices for circulatory support: first annual report. J Heart Lung Transplant. Oct 2008; 27(10): 1065-72. PMID 18926395
19. Aissaoui N, Morshuis M, Maoulida H, et al. Management of end-stage heart failure patients with or without ventricular assist device: an observational comparison of clinical and economic outcomes. Eur J Cardiothorac Surg. Jan 01 2018; 53(1): 170-177. PMID 28950304
20. Schmitto JD, Pya Y, Zimpfer D, et al. Long-term evaluation of a fully magnetically levitated circulatory support device for advanced heart failure-two-year results from the HeartMate 3 CE Mark Study. Eur J Heart Fail. Jan 2019; 21(1): 90-97. PMID 30052304

21. Gustafsson F, Shaw S, Lavee J, et al. Six-month outcomes after treatment of advanced heart failure with a full magnetically levitated continuous flow left ventricular assist device: report from the ELEVATE registry. Eur Heart J. Oct 01 2018; 39(37): 3454-3460. PMID 30165521
22. Pagani FD, Mehra MR, Cowger JA, et al. Clinical outcomes and healthcare expenditures in the real world with left ventricular assist devices - The CLEAR-LVAD study. J Heart Lung Transplant. May 2021; 40(5): 323-333. PMID 33744086
23. Mehra MR, Cleveland JC, Uriel N, et al. Primary results of long-term outcomes in the MOMENTUM 3 pivotal trial and continued access protocol study phase: a study of 2200 HeartMate 3 left ventricular assist device implants. Eur J Heart Fail. Aug 2021; 23(8): 1392-1400. PMID 33932272
24. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.
25. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med. Nov 15 2001; 345(20): 1435-43. PMID 11794191
26. Park SJ, Tector A, Piccioni W, et al. Left ventricular assist devices as destination therapy: a new look at survival. J Thorac Cardiovasc Surg. Jan 2005; 129(1): 9-17. PMID 15632819
27. Long JW, Kfoury AG, Slaughter MS, et al. Long-term destination therapy with the HeartMate XVE left ventricular assist device: improved outcomes since the REMATCH study. Congest Heart Fail. 2005; 11(3): 133-8. PMID 15947534
28. Rogers JG, Pagani FD, Tatooles AJ, et al. Intrapericardial Left Ventricular Assist Device for Advanced Heart Failure. N Engl J Med. Feb 02 2017; 376(5): 451-460. PMID 28146651
29. Estep JD, Starling RC, Horstmanshof DA, et al. Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients: Results From the ROADMAP Study. J Am Coll Cardiol. Oct 20 2015; 66(16): 1747-1761. PMID 26483097
30. Starling RC, Estep JD, Horstmanshof DA, et al. Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients: The ROADMAP Study 2-Year Results. JACC Heart Fail. Jul 2017; 5(7): 518-527. PMID 28396040
31. Jorde UP, Kushwaha SS, Tatooles AJ, et al. Results of the destination therapy post-food and drug administration approval study with a continuous flow left ventricular assist device: a prospective study using the INTERMACS registry (Interagency Registry for Mechanically Assisted Circulatory Support). J Am Coll Cardiol. May 06 2014; 63(17): 1751-7. PMID 24613333

32. Rogers JG, Butler J, Lansman SL, et al. Chronic mechanical circulatory support for inotrope-dependent heart failure patients who are not transplant candidates: results of the INTrEPID Trial. J Am Coll Cardiol. Aug 21 2007; 50(8): 741-7. PMID 17707178
33. Arnold SV, Jones PG, Allen LA, et al. Frequency of Poor Outcome (Death or Poor Quality of Life) After Left Ventricular Assist Device for Destination Therapy: Results From the INTERMACS Registry. Circ Heart Fail. Aug 2016; 9(8). PMID 27507111
34. Mehra MR, Goldstein DJ, Cleveland JC, et al. Five-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial. JAMA. Sep 27 2022; 328(12): 1233-1242. PMID 36074476
35. Acharya D, Loyaga-Rendon RY, Pamboukian SV, et al. Ventricular Assist Device in Acute Myocardial Infarction. J Am Coll Cardiol. Apr 26 2016; 67(16): 1871-80. PMID 27102502
36. Wever-Pinzon O, Drakos SG, McKellar SH, et al. Cardiac Recovery During Long-Term Left Ventricular Assist Device Support. J Am Coll Cardiol. Oct 04 2016; 68(14): 1540-53. PMID 27687196
37. Topkara VK, Garan AR, Fine B, et al. Myocardial Recovery in Patients Receiving Contemporary Left Ventricular Assist Devices: Results From the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). Circ Heart Fail. Jul 2016; 9(7). PMID 27402861
38. Maybaum S, Mancini D, Xydas S, et al. Cardiac improvement during mechanical circulatory support: a prospective multicenter study of the LVAD Working Group. Circulation. May 15 2007; 115(19): 2497-505. PMID 17485581
39. Agrawal S, Garg L, Shah M, et al. Thirty-Day Readmissions After Left Ventricular Assist Device Implantation in the United States: Insights From the Nationwide Readmissions Database. Circ Heart Fail. Mar 2018; 11(3): e004628. PMID 29519902
40. Dickstein K, Cohen-Solal A, Filippatos G, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM). Eur Heart J. Oct 2008; 29(19): 2388-442. PMID 18799522
41. Bulic A, Maeda K, Zhang Y, et al. Functional status of United States children supported with a left ventricular assist device at heart transplantation. J Heart Lung Transplant. Aug 2017; 36(8): 890-896. PMID 28363739

42. Wehman B, Stafford KA, Bittle GJ, et al. Modern Outcomes of Mechanical Circulatory Support as a Bridge to Pediatric Heart Transplantation. Ann Thorac Surg. Jun 2016; 101(6): 2321-7. PMID 26912304
43. Fraser CD, Jaquiss RD, Rosenthal DN, et al. Prospective trial of a pediatric ventricular assist device. N Engl J Med. Aug 09 2012; 367(6): 532-41. PMID 22873533
44. Blume ED, Rosenthal DN, Rossano JW, et al. Outcomes of children implanted with ventricular assist devices in the United States: First analysis of the Pediatric Interagency Registry for Mechanical Circulatory Support (PediMACS). J Heart Lung Transplant. May 2016; 35(5): 578-84. PMID 27009673
45. Almond CS, Morales DL, Blackstone EH, et al. Berlin Heart EXCOR pediatric ventricular assist device for bridge to heart transplantation in US children. Circulation. Apr 23 2013; 127(16): 1702-11. PMID 23538380
46. Jordan LC, Ichord RN, Reinhartz O, et al. Neurological complications and outcomes in the Berlin Heart EXCOR® pediatric investigational device exemption trial. J Am Heart Assoc. Jan 22 2015; 4(1): e001429. PMID 25613996
47. Chen S, Lin A, Liu E, et al. Outpatient Outcomes of Pediatric Patients with Left Ventricular Assist Devices. ASAIO J. 2016; 62(2): 163-8. PMID 26720740
48. Conway J, Al-Aklabi M, Granoski D, et al. Supporting pediatric patients with short-term continuous-flow devices. J Heart Lung Transplant. May 2016; 35(5): 603-9. PMID 27009672
49. Frazier OH, Rose EA, McCarthy P, et al. Improved mortality and rehabilitation of transplant candidates treated with a long-term implantable left ventricular assist system. Ann Surg. Sep 1995; 222(3): 327-36; discussion 336-8. PMID 7677462
50. Bank AJ, Mir SH, Nguyen DQ, et al. Effects of left ventricular assist devices on outcomes in patients undergoing heart transplantation. Ann Thorac Surg. May 2000; 69(5): 1369-74; discussion 1375. PMID 10881807
51. Shuhaiber JH, Hur K, Gibbons R. The influence of preoperative use of ventricular assist devices on survival after heart transplantation: propensity score matched analysis. BMJ. Feb 10 2010; 340: c392. PMID 20147346
52. Alba AC, McDonald M, Rao V, et al. The effect of ventricular assist devices on long-term post-transplant outcomes: a systematic review of observational studies. Eur J Heart Fail. Jul 2011; 13(7): 785-95. PMID 21551162

53. Deo SV, Sung K, Daly RC, et al. Cardiac transplantation after bridged therapy with continuous flow left ventricular assist devices. Heart Lung Circ. Mar 2014; 23(3): 224-8. PMID 23954004
54. Grimm JC, Sciortino CM, Magruder JT, et al. Outcomes in Patients Bridged With Univentricular and Biventricular Devices in the Modern Era of Heart Transplantation. Ann Thorac Surg. Jul 2016; 102(1): 102-8. PMID 27068177
55. Davies RR, Russo MJ, Hong KN, et al. The use of mechanical circulatory support as a bridge to transplantation in pediatric patients: an analysis of the United Network for Organ Sharing database. J Thorac Cardiovasc Surg. Feb 2008; 135(2): 421-7, 427.e1. PMID 18242279
56. Copeland JG, Smith RG, Arabia FA, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med. Aug 26 2004; 351(9): 859-67. PMID 15329423
57. Copeland JG, Copeland H, Gustafson M, et al. Experience with more than 100 total artificial heart implants. J Thorac Cardiovasc Surg. Mar 2012; 143(3): 727-34. PMID 22245242
58. Food and Drug Administration. Summary of Safety and Probable Benefit - H040006: AbioCor Implantable Replacement Heart. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf.
59. Dowling RD, Gray LA, Etoch SW, et al. Initial experience with the AbioCor implantable replacement heart system. J Thorac Cardiovasc Surg. Jan 2004; 127(1): 131-41. PMID 14752423
60. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. ASAIO J. 2014; 60(6): 626-34. PMID 25158888
61. Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. World J Cardiol. Jan 26 2016; 8(1): 98-111. PMID 26839661
62. Burkhoff D, Cohen H, Brunckhorst C, et al. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. Am Heart J. Sep 2006; 152(3): 469.e1-8. PMID 16923414
63. Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol. Nov 04 2008; 52(19): 1584-8. PMID 19007597
64. Thiele H, Sick P, Boudriot E, et al. Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute

myocardial infarction complicated by cardiogenic shock. Eur Heart J. Jul 2005; 26(13): 1276-83. PMID 15734771
65. Ouweneel DM, Eriksen E, Sjauw KD, et al. Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction. J Am Coll Cardiol. Jan 24 2017; 69(3): 278-287. PMID 27810347
66. Karami M, Eriksen E, Ouweneel DM, et al. Long-term 5-year outcome of the randomized IMPRESS in severe shock trial: percutaneous mechanical circulatory support vs. intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. Eur Heart J Acute Cardiovasc Care. Dec 06 2021; 10(9): 1009-1015. PMID 34327527
67. Schrage B, Ibrahim K, Loehn T, et al. Impella Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock. Circulation. Mar 05 2019; 139(10): 1249-1258. PMID 30586755
68. Sieweke JT, Berliner D, Tongers J, et al. Mortality in patients with cardiogenic shock treated with the Impella CP microaxial pump for isolated left ventricular failure. Eur Heart J Acute Cardiovasc Care. Mar 2020; 9(2): 138-148. PMID 29405734
69. Schäfer A, Werner N, Burkhoff D, et al. Influence of Timing and Predicted Risk on Mortality in Impella-Treated Infarct-Related Cardiogenic Shock Patients. Front Cardiovasc Med. 2020; 7: 74. PMID 32478095
70. Griffith BP, Anderson MB, Samuels LE, et al. The RECOVER I: a multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. J Thorac Cardiovasc Surg. Feb 2013; 145(2): 548-54. PMID 22405676
71. Lemaire A, Anderson MB, Lee LY, et al. The Impella device for acute mechanical circulatory support in patients in cardiogenic shock. Ann Thorac Surg. Jan 2014; 97(1): 133-8. PMID 24090575
72. Lauten A, Engström AE, Jung C, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circ Heart Fail. Jan 2013; 6(1): 23-30. PMID 23212552
73. Ouweneel DM, de Brabander J, Karami M, et al. Real-life use of left ventricular circulatory support with Impella in cardiogenic shock after acute myocardial infarction: 12 years AMC experience. Eur Heart J Acute Cardiovasc Care. Jun 2019; 8(4): 338-349. PMID 30403366
74. Ait Ichou J, Larivée N, Eisenberg MJ, et al. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. Catheter Cardiovasc Interv. Jun 2018; 91(7): 1250-1260. PMID 28941078

75. Briasoulis A, Telila T, Palla M, et al. Meta-Analysis of Usefulness of Percutaneous Left Ventricular Assist Devices for High-Risk Percutaneous Coronary Interventions. Am J Cardiol. Aug 01 2016; 118(3): 369-75. PMID 27265673
76. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation. Oct 02 2012; 126(14): 1717-27. PMID 22935569
77. Reddy YM, Chinitz L, Mansour M, et al. Percutaneous left ventricular assist devices in ventricular tachycardia ablation: multicenter experience. Circ Arrhythm Electrophysiol. Apr 2014; 7(2): 244-50. PMID 24532564
78. Aryana A, Gearoid O'Neill P, Gregory D, et al. Procedural and clinical outcomes after catheter ablation of unstable ventricular tachycardia supported by a percutaneous left ventricular assist device. Heart Rhythm. Jul 2014; 11(7): 1122-30. PMID 24732372
79. Kar B, Gregoric ID, Basra SS, et al. The percutaneous ventricular assist device in severe refractory cardiogenic shock. J Am Coll Cardiol. Feb 08 2011; 57(6): 688-96. PMID 20950980
80. Kirklin JK, Pagani FD, Goldstein DJ, et al. American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation guidelines on selected topics in mechanical circulatory support. J Heart Lung Transplant. Mar 2020; 39(3): 187-219. PMID 31983666
81. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. Aug 08 2017; 136(6): e137-e161. PMID 28455343
82. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Oct 15 2013; 62(16): e147-239. PMID 23747642
83. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. May 03 2022; 145(18): e876-e894. PMID 35363500

84. Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. Circulation. Nov 27 2012; 126(22): 2648-67. PMID 23109468
85. Bernhardt AM, Copeland H, Deswal A, et al. The International Society for Heart and Lung Transplantation/Heart Failure Society of America Guideline on Acute Mechanical Circulatory Support. J Heart Lung Transplant. Apr 2023; 42(4): e1-e64. PMID 36805198
86. Rihal CS, Naidu SS, Givertz MM, et al. 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care: Endorsed by the American Heart Assocation, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention. J Am Coll Cardiol. May 19 2015; 65(19): e7-e26. PMID 25861963
87. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). 2020; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=360&ncdver=2&keyword=ventricular%20assist&keywordType=starts&areaId=all&docType=NCD&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact.

Policy History

Original Effective Date: 01/20/2010
Current Effective Date: 12/11/2023

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
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
11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. Policy statements revised to remove outdated eligibility criteria, but intent unchanged.
11/03/2022	Medical Policy Committee review

Policy # 00246
Original Effective Date: 01/20/2010
Current Effective Date: 12/11/2023

11/09/2022 Medical Policy Implementation Committee approval. No change to coverage.
11/02/2023 Medical Policy Committee review
11/08/2023 Medical Policy Implementation Committee approval. Minor changes to coverage. Intent unchanged.
Next Scheduled Review Date: 11/2024

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 2022 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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Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246
Original Effective Date: 01/20/2010
Current Effective Date: 12/11/2023

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, 33995, 33997, 93750
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	All related Diagnoses

*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. 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 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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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.