LOUISIANA BLUE

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.*

Implantable Ventricular Assist Devices

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 individuals who are unable to be weaned off cardiopulmonary bypass to be **eligible for coverage.****

When Services May Be 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.

Percutaneous Ventricular Assist Devices (pVADs)
Based on review of available data, the Company may consider an FDA-approved percutaneous ventricular assist devices for the treatment of cardiogenic shock to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for pVADs for the treatment of cardiogenic shock will be considered when the following criteria are met:

- Adult individual (18 years or older); AND
- Acute myocardial infarction of less than 36 hours duration with one of the following findings:
    - ST- segment elevation myocardial infarction (STEMI) with new onset ST-segment elevation; OR

    - New onset ST segment depression or left bundle branch block (LBBB) and emergency angiography demonstrating acute proximal occlusion of coronary artery; AND
- Cardiogenic shock of less than 24 hours duration confirmed by hypotension (SBP < 100 mmHg or ongoing vasopressor support, e.g., dopamine/ norepinephrine or epinephrine), end-organ hypoperfusion with arterial lactate ≥2.5 mmol/L, and a left ventricle ejection fraction (LVEF) < 45%; AND
- Absence of ANY one of the following:
    - Individual has been resuscitated from out-of-hospital cardiac arrest and remained comatose on arrival to the cardiac catheterization laboratory with persistent Glasgow coma scale < 8 after return of spontaneous circulation;
      Note: Cardiac arrest occurring in the ambulance or after arrival to the hospital is NOT an exclusion criterion.
    - Severe right ventricle failure by echocardiogram;
    - Shock duration > 24 hours;
    - Other causes of shock, e.g., hypovolemia, sepsis, pulmonary embolism, anaphylaxis;
    - Shock due to mechanical complication to myocardial infarction
        - Papillary muscle rupture
        - Rupture of ventricular septum or ventricular free wall;
    - Severe aortic valve regurgitation or stenosis;
    - Established diagnosis of severe peripheral arterial obstructive disease or abnormalities of the aorta that would preclude pVAD placement;
    - Presence of a mechanical aortic valve prosthesis;
    - Left ventricle thrombus;
    - Infective endocarditis.

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 other 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.

Some ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. The DeBakey®‡ VAD Child device and the Berlin Heart EXCOR Pediatric VAD have FDA approval through the humanitarian device exemption process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant (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. The HeartMate3™‡ received approval for expanded approval for pediatric patients with advanced refractory left ventricular heart failure in 2020.

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 (i.e., 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 2024 report from the American Heart Association and based on data collected from 2017 to 2020, roughly 6.7 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 had a reported survival rate of nearly 92% or transplants performed in 2022. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

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. The HeartMate II and HeartMate 3 left VAD systems were recalled in April 2024 due to extrinsic outflow graft obstruction that can obstruct the device making it less effective. The recall was a corrective recall, and the devices remain on the market.

Table 1. Available Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
DeBakey VAD Child	MicroMed	Feb 2004	HDE	H030003	Bridge to transplant in children 5-16 y
HeartMate II	Thoratec (Abbott)	Apr 2008	PMA	P060040	Bridge to transplant and destination

CentriMag	Thoratec (Abbott)	Dec 2019	PMA	P170038	Postcardiotomy, bridge to decision
Berlin Heart EXCOR Pediatric VAD	Berlin	Jun 2017	PMA	P160035	Bridge to transplant or recovery
HeartMate 3 Left Ventricular Assist System	Thoratec (Abbott)	Aug 2017 Oct 2018	PMA PMA	P160054 P160054/S008	Bridge to transplant and 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 (LivaNova)	Sep 2011	510(k)	K110493	Temporary left ventricular bypass of ≤6 h
Impella CP	Abiomed	Nov 2016	PMA	P140003	• Temporary (≤6 hours) ventricular support devices indicated for use during high-risk PCI • Temporary ventricular support for ≤4 days in cardiogenic shock
Impella 5.5	Abiomed	Nov 2016	PMA	P140003	Temporary ventricular support for ≤14 days in cardiogenic shock

FDA: U.S. Food and Drug Administration; PCI: percutaneous coronary intervention; 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 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 individuals 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 infarct-related cardiogenic shock who receive a percutaneous VAD (pVAD), the evidence includes three small, randomized trials that did not show a clinical benefit of microaxial flow pumps, registry studies that showed excess bleeding among patients who received a microaxial pump, and a more recent international, multicenter, randomized, open-label trial funded by the Danish Heart Foundation and Abiomed (DanGer Shock trial, NEJM 4/2024). DanGer Shock trial tested the hypothesis that routine use of a microaxial flow pump in addition to standard guideline-directed therapies in patients with STEMI-related cardiogenic shock results in a lower mortality than standard care alone. Patients with ST segment elevation myocardial infarction and cardiogenic shock were assigned to receive a microaxial flow pump (Impella CP) plus standard care or standard of care alone. The primary end point was death from any cause at 180 days (6 months). A composite safety end point was severe bleeding, limb ischemia, hemolysis, device failure, or worsening aortic regurgitation. From January 2013 through July 2023 a total of 1211 patients underwent screening. A total of 360 adult patients underwent randomization, 355 were included in final analysis (179 in the microaxial-flow-pump and 176 in the standard-care group). The median age of the patients was 67 years, and 79.2% were men. The median arterial lactate level was 4.5 mmol/L, the median systolic BP was 82 mm Hg, and the median LV EF was 25%. The trial was conducted in a more homogenous patient population (a mandatory elevation in arterial lactate level in the absence of a cardiac arrest led to the identification of a patient population with profound LV failure). In the microaxial-flow-pump group, treatment was escalated to another mechanical circulatory support system in 28 patients (15.6%), and in the standard-care group in 37 patients (21%). Death from any cause occurred in 82 of 179 patients (45.8%) in the microaxial-flow-pump group and in 103 of 176 patients (58.5%) in the standard-care group (hazard ratio, 0.74; 95% confidence interval 0.55 to 0.99; P=0.04). The number needed to treat to avoid 1 death was 8. A composite safety end-point event occurred in 43 patients (24.0%) in the microaxial-flow-pump group and in 11 patients (6.2%) in the standard-care group (relative risk, 4.74; 95% CI, 2.36 to 9.55). In the microaxial-flow-pump group, the number needed to harm was 6. The relative risk (pump group vs. standard-care group) of moderate or severe bleeding was 2.06, of limb ischemia 5.15, and of sepsis with a positive blood culture 2.79. Renal-replacement therapy was administered to 75 patients (41.9%) in the pump group and to 47 patients (26.7%) in the standard-care group (relative risk, 1.98; 95% CI, 1.27 to 3.09). This considerably higher use of renal-replacement therapy is higher than that observed in the extracorporeal life support trial (ECLS-SHOCK trial). Authors noted that it remains a priority to address the prevention of serious adverse events that occur as a result of treatment with a microaxial flow pump. Trial

limitations include strict inclusion and exclusion criteria; the results cannot be extrapolated to patients who remain comatose after cardiac arrest, patients without ST-segment elevation myocardial infarction, patients without an elevation in the arterial lactate level, and patients who have more prominent biventricular failure. The trial was conducted in a small number of centers in Denmark, Germany, and the United Kingdom, so results may differ in health care systems in other countries with more racial diversity. The trial was not blinded therefore authors could not exclude the possible effect on therapeutic decisions made by treating physicians. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Clinical input was obtained and supported coverage criteria that are based on the inclusion and exclusion criteria in the DanGer Shock trial, which is also consistent with the 2025 ACC/AHA Joint Committee on Clinical Practice Guidelines (Guideline for the management of patients with acute coronary syndromes).

For other 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 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.

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 generally not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures.

The PROTECT II trial (10/2012) lead to the FDA approval of Impella as a temporary support for high-risk percutaneous cardiac interventions. Study included participants with PCI on an unprotected left main or last patent coronary vessel with LVEF $\leq$ 35%, or PCI for 3 vessel disease with LVEF $\leq$ 30%, and excluded patients with myocardial infarction, LV thrombus, PLT count $\leq$ 75,000/ mm3, creatinine $\geq$ 4 mg/dL, or severe PVD precluding passage of the catheter. The primary endpoint of

30-day MAE in the PROTECT II study occurred in 34.3% of the per protocol (PP) patients in the Impella 2.5 arm compared with 42.2% of PP patients in the IABP arm (P=0.092). This study had important limitations. Because of the determination of futility, only 69% (452) of the planned enrollment occurred. A significant learning curve occurred in this trial with improvement in safety for Impella-supported patients in the last half of the trial. The trial did not enroll the number of patients it was powered for, therefore definitive statements concerning the primary end point are speculative. The trial could not be blinded of the presence of Impella support which led to a greater and more aggressive use of rotational atherectomy, and the differences confounded the analysis. Because the difference in 30-day major adverse events did not reach statistical significance for the entire study, the analysis of 90-day events remains exploratory.

Restore EF study (8/2022) was largest to date study looking at LV EF changes 30 days after high-risk PCI. It was an observational nonrandomized multicenter retrospective analysis of prospectively collected observational data set to assess 90-day LVEF in patients who survived with no additional procedure prior to 90-day assessment. 36 out of 495 screened patients (7.3%) who died before day 60 were excluded from assessment; 406 patients were evaluated. The study reported 30-day mortality of 6.9% (all screened patients), increasing to 9.5% at 180 days. Authors concluded that in an ideal cohort there is a signal that high-risk PCI affords improvement in 90-day LV EF (from median 35% to 45% with P<.0001, most pronounced in those with a baseline LVEF $\leq$ 20%, no change in patients with LVEF > 45% at baseline) along with significant relief of angina and heart failure symptoms, and that this hypothesis-generating finding merits assessment in large studies and randomized controlled trials. Important limitations include the lack of a comparator, investigator-reported data with no angiographic or echocardiographic core lab, or independent clinical events committee adjudication, and unknown impact on LVEF from optimal heart failure medical therapy (data on medications were not collected). A significant number of patients (61.8%) who were included in the final study population did not undergo 90-day follow-up LVEF assessment (due to patients missing appointment or physician not ordering LVEF assessment).

The PROTECT III study was sponsored by Abiomed. It was a prospective, single-arm, FDA post-marketing approval (PMA) study of Impella 2.5®‡ and Impella CP®‡ in high-risk PCI. Trial included 898 patients enrolled at 45 sites in the United States between 3/2017 and 7/2019. Using cVAD registry database data, PROTECT III demonstrates a reduction in the primary endpoint of death, stroke, myocardial infarction and repeat procedures at 90 days with Impella-supported protected PCI, compared to PROTECT II.

Impella-supported PCI in high-risk patients with complex coronary artery disease and reduced LV function trial sponsored by Abiomed (the PROTECT IV trial, NCT04763200) is currently recruiting participants. It is an on-label, prospective, multi-center randomized controlled trial that is designed to provide the level of clinical evidence needed to achieve a global class I guideline recommendation (a strong recommendation, indicating that intervention is effective and should be performed in most patients in most circumstances) for Impella in high-risk PCI. The purpose of this study is to assess if using the Impella®‡ CP (or Impella® 2.5)‡ device during high-risk PCI in patients with reduced

left-sided heart function will result in an improvement in symptoms, heart function and health outcomes after a PCI, compared to the current standard of care. Inclusion criteria: adult patients (18-90 years of age) with LVEF ≤ 40% in setting of chronic coronary syndrome or NSTEMI, or STEMI ≥ 24 hours and < 30 days after symptom onset and LVEF ≤ 30%, and need of complex PCI (triple vessel disease, left main disease, ostial LAD and ostial LCX disease, or intervention of the last remaining vessel). Estimated study completion is 10/2027.

There is a lack of large-scale, high-quality RCTs demonstrating clear clinical benefits in the use of any of the mechanical circulatory support (MCS) devices during high-risk PCI. European Society of Cardiology guidelines did not make specific recommendations on the use of MCS during revascularization while the American College of Cardiology made only a class IIb recommendation (weak recommendation for which it is unknown whether benefit will outweigh the risk) for the use of hemodynamic support device as an adjunct to complex PCI for selected high-risk patients to prevent hemodynamic compromise. Ongoing and future research will shed light on unanswered questions including those around the definition of complex, high-risk and indicated PCI, patient selection, device selection, evaluation of new devices and timing of support initiation.

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.

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.

2025 ACC/AHA/ACEP/ NAEMSP/ SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines (based on a comprehensive literature search from July 2023 to April 2024) included grade 2a recommendation (a moderate recommendation for which benefit most likely outweighs the risk): “In selected patients with STEMI and severe or refractory cardiogenic shock, insertion of a microaxial intravascular flow pump is reasonable to reduce death.” Based on the results of the DanGer-SHOCK trial, “use of a microaxial flow pump is reasonable to reduce mortality in patients with STEMI and cardiogenic shock who have clinical features consistent with the inclusion criteria of the DanGer-SHOCK trial. In particular, patients with STEMI who present with SCAI shock stages C, D, or E, who are noncomatose and have adequate peripheral vasculature to accommodate large-bore access are reasonable candidates for the microaxial flow pump.”

One of the recommendations for mechanical complications of ACS is related to mechanical circulatory support (MCS) devices (2a): "In patients with a mechanical complication of ACS, short-term MCS devices are reasonable for hemodynamic stabilization as a bridge to surgery." It is noted that no RCTs have evaluated the role of MCS devices in improving clinical outcomes in the setting of mechanical complications. In patients with ventricular septal rupture, the use of an IABP has been shown to reduce left-to-right shunting and improve hemodynamics in patients with and without cardiogenic shock. Favorable hemodynamic effects with IABP are also noted with acute ischemic mitral regurgitation."

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			
NCT01627821[a]	Evaluation of the Jarvik 2000 Left Ventricular Assist System With Post-Auricular Connector--Destination Therapy Study	350	Mar 2025
NCT02232659[a]	SynCardia 70cc Temporary Total Artificial Heart (TAH-t) for Destination Therapy (DT)	38	May 2022 (last

NCT No.	Trial Name	Planned Enrollment	Completion Date
			updated Mar 2021)
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	102	Dec 2024
NCT04768322	Left Ventricular Assist Device (LVAD) Versus Guideline Recommended Medical Therapy in Ambulatory Advanced Heart Failure Patients (GDMT)	92	Feb 2027
Unpublished			
NCT02326402[a]	THEME Registry: TandemHeart Experiences and Methods	365	Jan 2023

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: 05/01/2025

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

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Current Effective Date: 05/01/2025

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
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.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Coverage for percutaneous ventricular assist devices (PVADs) changed from investigational to eligible for coverage with criteria.

Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 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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for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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	I21 -121.02, 1211-121.19, 1212-121.29, 121.3, 121.4, 121.9, 122-I22.9, R57.0, T81.11XA-T81.11XS

*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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.