



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

**Policy #** 00246

**Original Effective Date:** 01/20/2010

**Current Effective Date:** 12/14/2020

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

### When Services Are Eligible for Coverage

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

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

#### ***Bridge to Transplantation***

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

### ***Destination Therapy***

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

### Patient Selection Criteria

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

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

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

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

### ***Post-cardiotomy Setting/Bridge to Recovery***

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

## **When Services Are Considered Investigational**

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

### ***Other Indications***

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

### **Policy Guidelines**

Only 2 ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration for the pediatric population. The DeBakey VAD Child device and the Berlin Heart EXCOR Pediatric VAD have Food and Drug Administration approval through the humanitarian device exemption process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant (ie, a bridge to transplant) while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

## **Background/Overview**

### **Heart Failure**

Heart failure may be the consequence of a number of etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and has survival rates at 1, 3, and 5 years of about 91%, 85%, and 78%, respectively. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

### **Treatment**

#### **Ventricular Assist Devices**

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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 cardiectomy affecting the ventricular wall may preclude VAD use.

### **Total Artificial Hearts**

Initial research into mechanical assistance for the heart focused on the TAH, a biventricular device that completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

A fully bioprosthetic TAH, which is fully implanted in the pericardial sac and is electrohydraulically actuated, has been developed and tested in two patients but is currently experimental.

### **Percutaneous Ventricular Assist Devices (VADs)**

Devices in which most of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Some circulatory assist devices are placed percutaneously (ie, are not implanted). They may be referred to as pVADs. A pVAD is placed through the femoral artery. Two different pVADs have been developed, the TandemHeart and the Impella device. In the TandemHeart System, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

### **FDA or Other Governmental Regulatory Approval**

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

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

Berlin Heart EXCOR <sup>®</sup> Pediatric VAD	Berlin	Dec 2011	HDE	H100004	Bridge to transplant
HeartWare <sup>®</sup> Ventricular Assist System	HeartWare	Dec 2012	PMA	P100047	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.

### Ventricular Assist Devices

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

### **Total Artificial Heart**

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

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

### Percutaneous VADs (Circulatory Assist Devices)

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

### **Comparative Efficacy of Left VAD Devices**

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

### **Rationale/Source**

A ventricular assist device (VAD) is mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy in those not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

#### **Ventricular Assist Device**

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

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

#### **Total Artificial Heart**

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

### **Percutaneous Ventricular Assist Device**

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

## **Supplemental Information**

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

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

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

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

### **Practice Guidelines and Position Statements**

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

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

### American College of Cardiology Foundation et al

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

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

These 2013 guidelines also noted:

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

### American Heart Association

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

**Table 5. 2012 Guidelines on MCS**

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

### Heart Failure Society of America

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

HF: heart failure; SOE: strength of evidence.

### Society for Cardiovascular Angiography and Interventions et al

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

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

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

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

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

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

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

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 7.

**Table 7. Summary of Key Trials**

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

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

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Total Artificial Hearts and Implantable Ventricular Assist Devices”, 7.03.11, 10:2020.
2. 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/#>.
3. Netuka I, Sood P, Pya Y, et al. Fully Magnetically Levitated Left Ventricular Assist System for Treating Advanced HF: A Multicenter Study. J Am Coll Cardiol. Dec 15 2015; 66(23): 2579-2589. PMID 26670056
4. Carpentier A, Latremouille C, Cholley B, et al. First clinical use of a bioprosthetic total artificial heart: report of two cases. Lancet. Oct 17 2015; 386(10003): 1556-63. PMID 26231456
5. Mehra MR, Naka Y, Uriel N, et al. A Fully Magnetically Levitated Circulatory Pump for Advanced Heart Failure. N Engl J Med. Feb 02 2017; 376(5): 440-450. PMID 27959709
6. Rogers JG, Pagani FD, Tatrooles 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
7. 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

8. 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
9. 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
10. Pruijsten RV, Lok SI, Kirkels HH, et al. Functional and haemodynamic recovery after implantation of continuous-flow left ventricular assist devices in comparison with pulsatile left ventricular assist devices in patients with end-stage heart failure. *Eur J Heart Fail*. Mar 2012; 14(3): 319-25. PMID 22294758
11. Lim KM, Constantino J, Gurev V, et al. Comparison of the effects of continuous and pulsatile left ventricular-assist devices on ventricular unloading using a cardiac electromechanics model. *J Physiol Sci*. Jan 2012; 62(1): 11-9. PMID 22076841
12. Kato TS, Chokshi A, Singh P, et al. Effects of continuous-flow versus pulsatile-flow left ventricular assist devices on myocardial unloading and remodeling. *Circ Heart Fail*. Sep 2011; 4(5): 546-53. PMID 21765125
13. Ventura PA, Alharethi R, Budge D, et al. Differential impact on post-transplant outcomes between pulsatile- and continuous-flow left ventricular assist devices. *Clin Transplant*. Jul-Aug 2011; 25(4): E390-5. PMID 21401721
14. Al-Sarie M, Rauf A, Kfoury AG, et al. Myocardial Structural and Functional Response After Long-Term Mechanical Unloading With Continuous Flow Left Ventricular Assist Device: Axial Versus Centrifugal Flow. *JACC Heart Fail*. Jul 2016; 4(7): 570-576. PMID 27179831
15. 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
16. 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
17. 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
18. Takayama H, Soni L, Kalesan B, et al. Bridge-to-decision therapy with a continuous-flow external ventricular assist device in refractory cardiogenic shock of various causes. *Circ Heart Fail*. Sep 2014; 7(5): 799-806. PMID 25027874

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

19. TEC Assessment Program. Ventricular assist devices in bridging to heart transplantation. 1996;Volume 11;Tab 26.
20. Goldstein DJ, Oz MC, Rose EA. Implantable left ventricular assist devices. *N Engl J Med.* Nov 19 1998; 339(21): 1522-33. PMID 9819452
21. 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
22. 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
23. 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
24. 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
25. 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
26. 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
27. Struber 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
28. 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
29. 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
30. 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
31. 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

32. 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
33. 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
34. 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
35. 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
36. 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
37. 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
38. Jordan LC, Ichord RN, Reinhartz O, et al. Neurological complications and outcomes in the Berlin Heart EXCOR(R) pediatric investigational device exemption trial. *J Am Heart Assoc*. Jan 22 2015; 4(1): e001429. PMID 25613996
39. Chen S, Lin A, Liu E, et al. Outpatient Outcomes of Pediatric Patients with Left Ventricular Assist Devices. *ASAIO J*. Mar-Apr 2016; 62(2): 163-8. PMID 26720740
40. 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
41. 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
42. 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

43. 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
44. 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
45. 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
46. 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
47. 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
48. 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
49. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002; Volume 17; Tab 19.
50. 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
51. 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
52. 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.* May-Jun 2005; 11(3): 133-8. PMID 15947534
53. 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
54. 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

55. Jorde UP, Kushwaha SS, Tatoes 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
56. 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
57. 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
58. 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
59. 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](https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf).
60. 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
61. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. *ASAIO J*. Nov-Dec 2014; 60(6): 626-34. PMID 25158888
62. 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
63. 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
64. 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
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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

66. 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
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. Schafer 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, Engstrom 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, Larivee 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

- 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. 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
84. Lindenfeld J, Albert NM, Boehmer JP, et al. HFSA 2010 Comprehensive Heart Failure Practice Guideline. *J Card Fail*. Jun 2010; 16(6): e1-194. PMID 20610207
85. 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 Association, 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

86. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). 2013; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=ventricular+assist+devices&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&>.

### **Policy History**

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

- 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

- 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
  - 10/01/2021 Coding update
- Next Scheduled Review Date: 11/2021

### **Coding**

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

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT,*

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

*and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana 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.*

CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	33927, 33928, 33929, 33975, 33976, 33977, 33978, 33979, 33980, 33981, 33982, 33983, 33990, 33991, 33992, 33993, 93750 Codes added eff 1/1/2021: 33995, 33997
HCPCS	L8698, Q0477, Q0478, Q0479, Q0480, Q0481, Q0482, Q0483, Q0484, Q0485, Q0486, Q0487, Q0488, Q0489, Q0490, Q0491, Q0492, Q0493, Q0494, Q0495, Q0496, Q0497, Q0498, Q0499, Q0500, Q0501, Q0502, Q0503, Q0504, Q0506, Q0507, Q0508, Q0509
ICD-10 Diagnosis	I09.81, I11.0, I13.0, I13.2, I50.20-I50.23, I50.30-I50.33, I50.40-I50.43, I50.9 Adding code eff 10/1/2021: I5A

\*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,

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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

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

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

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

‡ 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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Total Artificial Hearts and Implantable Ventricular Assist Devices

Policy # 00246

Original Effective Date: 01/20/2010

Current Effective Date: 12/14/2020

recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.