

MEDICAL POLICY – 7.03.11

Total Artificial Hearts and Implantable Ventricular Assist Devices

BCBSA Ref. Policy: 7.03.11

Effective Date: Nov. 1, 2020

Last Revised: Nov. 30, 2020

Replaces: N/A


RELATED MEDICAL POLICIES:

7.03.08 Heart/Lung Transplant

7.03.09 Heart Transplant

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [DOCUMENTATION REQUIREMENTS](#) | [CODING](#)
[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

Introduction

An implantable ventricular assist device (VAD) is a battery-operated mechanical pump that can help your heart pump blood out to the rest of your body. The VAD is surgically put in your body. It has a tube that pulls blood from the left ventricle (the main pumping chamber of the heart) and pumps the blood into the aorta (the main artery leaving the heart). The blood is then sent out to the rest of the body. Another device, called a total artificial heart (TAH), can be implanted in the chest to replace both of the lower pumping chambers in the heart. This policy identifies the criteria needed for a VAD or TAH to be covered as medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Device	Medical Necessity
Bridge to Transplantation	
Implantable ventricular assist devices (VADs) with FDA approval	<p>FDA approved ventricular assist devices (VADs) may be considered medically necessary as a bridge to heart transplantation for adult and pediatric (see Related Information) patients:</p> <ul style="list-style-type: none"> Who are currently listed as heart transplantation candidates and are not expected to survive until a donor heart can be obtained <p>OR</p> <ul style="list-style-type: none"> Who are undergoing evaluation to determine candidacy for heart transplantation
Total artificial hearts (TAHs) with FDA-approval	<p>FDA-approved total artificial hearts (TAHs) implantation may be considered medically necessary as a bridge to heart transplantation for patients with ALL of the following:</p> <ul style="list-style-type: none"> Biventricular failure who have no other reasonable medical or surgical treatment options <p>AND</p> <ul style="list-style-type: none"> They are ineligible for other univentricular or biventricular support devices <p>AND</p> <ul style="list-style-type: none"> They are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation <p>AND</p> <ul style="list-style-type: none"> They are not expected to survive until a donor heart can be obtained
Destination Therapy	
Implantable VADs with FDA approval	<p>FDA approved implantable VADs may be considered medically necessary as destination therapy for patients who meet ALL of the following:</p> <ul style="list-style-type: none"> They have end-stage heart failure <p>AND</p> <ul style="list-style-type: none"> They are ineligible for human heart transplant (see below) <p>AND</p> <ul style="list-style-type: none"> They meet the following REMATCH Study criteria:



Device	Medical Necessity
	<ul style="list-style-type: none"> ○ New York Heart Association class IV heart failure for ≥ 60 days, <p>OR</p> <ul style="list-style-type: none"> ○ New York Heart Association class III or IV for 28 days <p>AND</p> <ul style="list-style-type: none"> ○ they received ≥ 14 days of support with intra-aortic balloon pump <p>OR</p> <ul style="list-style-type: none"> ○ They are dependent on intravenous inotropic agents, with 2 failed weaning attempts <p>Additionally, patients must not be candidates for human heart transplant for ANY of the following reasons:</p> <ul style="list-style-type: none"> • Age > 65 years <p>OR</p> <ul style="list-style-type: none"> • Insulin-dependent diabetes with end-organ damage <p>OR</p> <ul style="list-style-type: none"> • Chronic renal failure (serum creatinine > 2.5 mg/dL for ≥ 90 days) <p>OR</p> <ul style="list-style-type: none"> • Presence of other clinically significant condition
Postcardiotomy Setting/Bridge to Recovery	
Implantable VADs with FDA approval	FDA approved implantable VADs may be considered medically necessary in patients who are postcardiotomy (following open-heart surgery) and are unable to be weaned off cardiopulmonary bypass.

Device	Investigational
Other applications of VADs or TAHs	<p>Other applications of implantable VADs or TAHs are considered investigational, including, but not limited to, the use of TAHs as destination therapy.</p> <p>The use of non-FDA-approved implantable VADs or TAHs is considered investigational.</p>



Device	Investigational
	<p>Percutaneous VADs are considered investigational for all indications. (eg, TandemHeart®, Impella® 2.5, Impella 5.0 System)</p>

Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met.

For implantable ventricular assist devices (VADs) as bridge therapy for adult and pediatric patients, the record should include clinical documentation that:

- Patient is currently listed as a heart transplant candidate but a heart is not yet available and patient’s own heart may not be able to keep patient alive until one is found
- OR**
- It’s used during the evaluation to see if patient is a candidate for a heart transplant

For total artificial hearts (TAHs) with FDA-approval–bridge therapy, the record should include clinical documentation of ALL of the following:

- Patient’s heart failure affects both sides of the heart and there are no other reasonable medical or surgical treatment options
- AND**
- Patient is ineligible for any other support devices
- AND**
- Patient is waiting for a donor heart or being evaluated for a donor heart
- AND**
- Patient is not expected to survive until a donor heart can be obtained

For implantable VADs with FDA approval– destination therapy, the record should include clinical documentation of ALL of the following:

- Patient has end-stage heart failure
 - Patient is not a candidate for human heart transplant due to the following reasons:
 - Age >65 years
- OR**
- Insulin-dependent diabetes with end-organ damage
- OR**
- Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days)
- OR**



Documentation Requirements

- Presence of other clinically significant condition
- Patient meets the following REMATCH study criteria:
 - New York Heart Association class IV heart failure for ≥ 60 days
- OR**
- New York Heart Association class III or IV for 28 days
- AND**
- They received ≥ 14 days of support with intra-aortic balloon pump
- OR**
- They are dependent on intravenous inotropic agents, with 2 failed weaning attempts

For implantable VADs with FDA approval – postcardiotomy, the record should include clinical documentation that:

- Patient had an open-heart surgery and is unable to be weaned off cardiopulmonary bypass

Coding

Code	Description
CPT	
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass



Code	Description
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transeptal puncture
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only (new code effective 1/1/21)
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion (new code effective 1/1/21)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.

Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.

Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

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. See [Regulatory Status](#) and [Ongoing and Unpublished Clinical Trials](#) sections below.

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. (See [Related Policies](#)) for further discussion of heart transplant candidacy.

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 m² or who have a distance between the sternum and 10th anterior rib of less than 10 cm, as measured by computed tomography scan.

Evidence Review

Description

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



Background

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.¹ 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 ventricular assist devices (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.²

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 cardiectomy affecting the ventricular wall may preclude VAD use.



Total Artificial Hearts

Initial research into mechanical assistance for the heart focused on the total artificial heart (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.³

Percutaneous 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 percutaneous VADs (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.

Summary of Evidence

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. Relevant outcomes are overall



survival, symptoms, functional outcomes, quality of life, 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 quality of life. 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. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, 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 heart transplant. Despite an increase in adverse events, both mortality and quality of life 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. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, 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. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, and treatment-related mortality and morbidity. Four randomized controlled trials of pVAD vs intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates associated 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 IABP who receive a pVAD, the evidence includes case series. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, 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 the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01633502	Effects of Advanced Mechanical Circulatory Support in Patients with ST Segment Elevation Myocardial Infarction	360	Jan 2023



NCT No.	Trial Name	Planned Enrollment	Completion Date
	Complicated by Cardiogenic Shock. The Danish Cardiogenic Shock Trial		
NCT02468778 ^a	Supporting Patients Undergoing High-Risk PCI Using a High-Flow Percutaneous Left Ventricular Support Device (SHIELD II)	716	Dec 2021
NCT01627821 ^a	Evaluation of the Jarvik 2000 Left Ventricular Assist System With Post-Auricular Connector--Destination Therapy Study	350	Dec 2020
NCT01966458 ^a	A Prospective, Randomized, Controlled, Unblinded, Multi-Center Clinical Trial to Evaluate the HeartWare® Ventricular Assist Device System for Destination Therapy of Advanced Heart Failure	494	Aug 2020
NCT02232659	SynCardia 70cc Temporary Total Artificial Heart (TAH-t) for Destination Therapy (DT)	38	Dec 2022
NCT02326402	THEME Registry: TandemHeart Experiences and Methods	200	Dec 2020
NCT01187368 ^a	A Prospective Study to Evaluate the Safety and Efficacy of the EVAHEART LVAS for Use as a Bridge-to-Transplant	399	Dec 2024
NCT02387112	Early Versus Emergency Left Ventricular Assist Device Implantation in Patients Awaiting Cardiac Transplantation	200	Dec 2022
NCT02459054	SynCardia 50cc Temporary Total Artificial Heart (TAH-t) as a Bridge to Transplant	72	Jun 2024

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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 two physician specialty societies and five 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 total artificial heart as



destination therapy. All providing input supported the use of implantable ventricular assist devices 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 an 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 2).⁷⁹ The guideline authors noted, “Compared with intra-aortic balloon pump (IABP), contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar.”

Table 2. 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.



The American College of Cardiology Foundation et al

In 2017 the American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of America published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA.⁸⁰ Left ventricular assist device was one 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 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.⁸¹ The guidelines categorized percutaneous ventricular assist devices (pVADs) and extracorporeal VADs as nondurable MCS devices. **Table 3** provides class IIA guidelines on MCS devices.

Table 3. 2017 Guidelines on Mechanical Circulatory Support (MCS)

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
"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 HFrEF with acute, profound hemodynamic compromise."	IIA	B
"Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HFrEF."	IIA	B

COE: class of evidence; HFrEF: 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 (AHA)

In 2012, the AHA () published recommendations for the use of MCS.⁸² These guidelines defined nondurable MCS as intraballoon pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. **Table 4** lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 4. 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."	IIAI	C
"These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF."	I	C



Recommendation	COE	LOE
"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.

The Heart Failure Society of America (HFSA)

In 2010, the Heart Failure Society of America published guidelines on surgical approaches to the treatment of heart failure.⁸³ **Table 5** lists recommendations on left VADs:

Table 5. Guidelines on Left Ventricular Assist Devices

Recommendation	SOE
Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant."	B
"Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center."	B
"Patients with refractory HF and hemodynamic instability, and/or compromised end-organ function, with relative contraindications to cardiac transplantation or permanent mechanical circulatory assistance expected to improve with time or restoration of an improved hemodynamic profile should be considered for urgent mechanical circulatory support as a 'bridge to decision.' These patients should be referred to a center with expertise in the management of patients with advanced HF."	C

HF: heart failure; SOE: strength of evidence.

Society for Cardiovascular Angiography and Interventions et al

in 2015, the Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America, the Society of Thoracic Surgeons, and the American College of Cardiology published a joint clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care.⁸⁴ This statement addressed intra-aortic balloon pumps, left atrial-to-aorta assist devices (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.

Medicare National Coverage

Medicare has a national coverage determination (NCD) for artificial hearts and related devices, including VADS.⁸⁵ The NCD mandates coverage for VADs in the postcardiotomy setting as long as the following conditions are met:

- The VAD has “approval from the FDA” for post-cardiotomy support.
- The VAD is “used according to the FDA-approved labeling instructions.”

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

- The VAD has approval from the 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 (LVEF) <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.

Regulatory Status

A number of mechanical circulatory support devices have been approved or cleared for marketing by the U.S. Food and Drug Administration (FDA). These devices are summarized in [Table 6](#) and [Table 7](#).

Table 6. Available Mechanical Circulatory Support Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
VADs					
Thoratec® IVAD	Thoratec	Aug 2004	PMA supplement	P870072	Bridge to transplant and postcardiotomy
DeBakey VAD® Child	MicroMed	Feb 2004	HDE	H030003	Bridge to transplant in children 5-16 y of age
HeartMate II®	Thoratec	Apr 2008	PMA	P060040	Bridge to transplant and destination



Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
CentriMag®	Levitronix (now Thoratec)	Oct 2008	HDE	H070004	Postcardiotomy
Berlin Heart EXCOR® Pediatric VAD	Berlin	Dec 2011	HDE	H100004	Bridge to transplant
HeartWare® Ventricular Assist System	HeartWare	Dec 2012 (see class I recall info below)	PMA	P100047	Bridge to transplant
HeartMate 3™ Left Ventricular Assist System	Thoratec	Aug 2017 Oct 2018 (see class I recall info below)	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® 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 postcardiotomy patients unable to be weaned from cardiopulmonary bypass. In June 2001, supplemental approval was given for a portable external driver to permit excursions within a 2-hour travel radius of the hospital when accompanied by a trained caregiver. In 2003, supplemental approval was given to market the device as Thoratec® Paracorporeal VAD. In 2004, supplemental approval was given to a modified device to be marketed as the Thoratec® Implantable VAD for the same indications. In 2008, supplemental approval was given to rescind Paracorporeal VAD use.



In August 2016, HeartWare® recalled its VAD Pumps due to a design flaw that was deemed by the FDA as potentially causing serious injuries or death (class I recall). The devices affected were manufactured and distributed from March 2006 and May 2018. FDA product codes 204 and 017.

A class I recall was issued for the HeartMate 3™ in April 2018 affecting all manufacturing dates. FDA product code: DSQ.

Total Artificial Heart

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

In 2006, the AbioCor® Implantable Replacement Heart System (Abiomed) was approved by the FDA through the humanitarian device exemption (H040006) process for use 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
- Unable to be weaned from biventricular support if on such support.

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



Percutaneous VADs (Circulatory Assist Devices)

Table 7. Available Mechanical Circulatory Support Devices

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

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

Comparative Efficacy of Left VAD Devices

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

The evidence of the comparative efficacy of centrifugal continuous-flow vs axial continuous-flow devices consists of two randomized controlled trials of two different centrifugal continuous-flow devices.^{4,5} 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 two-year results from MOMENTUM 3, which showed superiority of the HeartMate 3 device compared to HeartMate II on the composite primary outcome, survival at two years free of disabling stroke or reoperation to replace a malfunctioning device (relative risk 0.84; 95% confidence interval 0.78–0.91, $p < 0.001$).⁶ Prevalence of stroke at two years was lower in the HeartMate 3 than the HeartMate 2 group (10.1% vs 19.2%; $P = 0.02$).⁷ Measures of functional capacity and Health-Related Quality of Life did not differ between the two devices at six months.⁸ 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 two 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.⁹⁻¹³ 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.

References

1. 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/#> Accessed October 2020.
2. 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.
3. 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):1556-1563. PMID 26231456.
4. 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.
5. Rogers JG, Pagani FD, Tatooles AJ, et al. Intrapericardial left ventricular assist device for advanced heart failure. *N Engl J Med*. Feb 02 2017;376(5):451-460. PMID 28146651.
6. Mehra, M, Uriel, N, Naka, Y, et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. *N. Engl. J. Med.*, 2019 Mar 19;380(17). PMID 30883052.
7. Colombo, P, Mehra, M, Goldstein, D, et al. Comprehensive Analysis of Stroke in the Long-Term Cohort of the MOMENTUM 3 Study. *Circulation*, 2018 Dec 28;139(2). PMID 30586698.
8. Cowger, J, Naka, Y, Aaronson, K 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.*, 2017 Nov 21;37(1). PMID 29153637.
9. 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):319-325. PMID 22294758.
10. 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):11-19. PMID 22076841.



11. 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):546-553. PMID 21765125.
12. 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):E390-395. PMID 21401721.
13. 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.
14. 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):1871-1880. PMID 27102502.
15. 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):2497-2505. PMID 17485581.
16. 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* 2018 11(3):e004628. PMID 29519902.
17. 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.
18. TEC Assessment Program. Ventricular assist devices in bridging to heart transplantation. 1996;Volume 11;Tab 26.
19. Goldstein DJ, Oz MC, Rose EA. Implantable left ventricular assist devices. *N Engl J Med.* Nov 19 1998;339(21):1522-1533. PMID 9819452.
20. 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):675-683. PMID 23796152.
21. 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):1375-1382. PMID 21414534.
22. 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.* Oct 2007;34(3):275-281. PMID 17948075.
23. 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):1227-1234; discussion 1234-1225. PMID 18805167.
24. 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):885-896. PMID 17761592.
25. 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):832-840; discussion 832-840. PMID 18721570.
26. 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):289-294. PMID 18571932.
27. 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):1065-1072. PMID 18926395.
28. 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.* 2018 53(1). PMID 28950304.
29. Schmitto J, 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.,* 2018 Jul 28;21(1). PMID 30052304.



30. 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.*, 2018 Aug 31;39(37). PMID 30165521.
31. 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):2388-2442. PMID 18799522.
32. 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.
33. 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):2321-2327. PMID 26912304.
34. Fraser CD, Jr., Jaquiss RD, Rosenthal DN, et al. Prospective trial of a pediatric ventricular assist device. *N Engl J Med.* Aug 09 2012;367(6):532-541. PMID 22873533.
35. 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):578-584. PMID 27009673.
36. 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):1702-1711. PMID 23538380.
37. 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 2015;4(1):e001429. PMID 25613996.
38. 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):163-168. PMID 26720740.
39. 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):603-609. PMID 27009672.
40. 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):1247-1254. PMID 11955839.
41. 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):327-336; discussion 336- 328. PMID 7677462.
42. 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):1369-1374; discussion 1375. PMID 10881807.
43. 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.
44. 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):785-795. PMID 21551162.
45. 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):224-228. PMID 23954004.
46. 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):102-108. PMID 27068177.
47. 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):421-427, 427 e421. PMID 18242279.
48. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.



49. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term mechanical left ventricular assistance for end-stage heart failure. *N Engl J Med*. Nov 15 2001;345(20):1435-1443. PMID 11794191.
50. 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.
51. 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):133-138. PMID 15947534.
52. 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.
53. 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.
54. 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 6 2014;63(17):1751-1757. PMID 24613333.
55. 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):741-747. PMID 17707178.
56. Copeland JG, Smith RG, Arabia FA, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. *N Engl J Med*. Aug 26 2004;351(9):859-867. PMID 15329423.
57. Copeland JG, Copeland H, Gustafson M, et al. Experience with more than 100 total artificial heart implants. *J Thorac Cardiovasc Surg*. Mar 2012;143(3):727-734. PMID 22245242.
58. Food and Drug Administration. Summay of Safety and Probable Benefit - H040006: AbioCor Implantable Replacement Heart. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf. Accessed October 2020.
59. Dowling RD, Gray LA, Jr., Etoch SW, et al. Initial experience with the AbioCor implantable replacement heart system. *J Thorac Cardiovasc Surg*. Jan 2004;127(1):131-141. PMID 14752423.
60. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. *ASAIO J*. Nov-Dec 2014;60(6):626-634. PMID 25158888.
61. Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. *World J Cardiol*. Jan 26 2016;8(1):98-111. PMID 26839661.
62. Burkhoff D, Cohen H, Brunckhorst C, et al. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. *Am Heart J*. Sep 2006;152(3):469 e461-468. PMID 16923414.
63. Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. *J Am Coll Cardiol*. Nov 4 2008;52(19):1584-1588. PMID 19007597.
64. Ouweneel DM, Eriksen E, Sjaaw 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.
65. 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):1276-1283. PMID 15734771.
66. Schrage, B, Ibrahim, K, Loehn, T, et al. Impella Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock. *Circulation*, 2018 Dec 28;139(10). PMID 30586755.



67. 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
68. 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
69. 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):548-554. PMID 22405676.
70. 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):133-138. PMID 24090575.
71. 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.
72. Ouweneel, D, 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*, 2018 Nov 8;8(4). PMID 30403366.
73. Ait Ichou, J, Larivée, N, Eisenberg, M, et al. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. *Catheter Cardiovasc Interv*, 2017 Sep 25;91(7). PMID 28941078.
74. 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 1 2016;118(3):369-375. PMID 27265673.
75. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. *Circulation*. Oct 2 2012;126(14):1717-1727. PMID 22935569.
76. 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):244-250. PMID 24532564.
77. 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):1122-1130. PMID 24732372.
78. Kar B, Gregoric ID, Basra SS, et al. The percutaneous ventricular assist device in severe refractory cardiogenic shock. *J Am Coll Cardiol*. Feb 8 2011;57(6):688-696. PMID 20950980.
79. 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
80. 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*. Apr 28 2017 136(6):e137-e161. PMID 28455343.
81. 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.
82. 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):2648-2667. PMID 23109468.
83. 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
84. 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.

85. 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=gAAAACAAAAA&>. Accessed October 2020.

History

Date	Comments
04/14/98	Add to Surgery Section - New Policy
06/01/99	Replace policy - Policy updated to include new FDA-approved devices.
06/27/00	Replace policy - Scheduled review; no criteria changes.
11/12/02	Replace policy - Policy reviewed: Rationale section expanded, references added. Policy statement on use of VADs in patients who are not transplant candidates deleted; this topic will be addressed in a separate policy. Policy statement otherwise unchanged.
04/15/03	Replace policy - Policy statement revised to include 2002 TEC Assessment conclusions regarding VADs in patients who are not transplant candidates, ie, "destination" therapy. Title changed from Ventricular Assist Devices as a Bridge to Heart Transplantation.
10/16/03	Replace policy - Policy statement revised to limit medically necessary indications to FDA approved devices.
02/10/04	Replace policy - Policy statement added regarding investigational status of total artificial hearts. Additional 2003 Category III CPT codes added.
06/14/05	Replace policy - Policy statement revised to indicate that a total artificial heart may be considered medically necessary as a bridge to transplant, based on FDA approval for that indication.
04/21/06	Codes Updated - No other changes
05/26/06	Scope and Disclaimer Updates - No other changes.
07/11/06	Replace policy - Policy updated with literature review; references added; policy statement unchanged.
11/14/06	Replace policy - Policy updated with FDA approval of total artificial heart. Policy statement unchanged; total artificial hearts are investigational. References added.
12/11/06	Codes Updated - No other changes



Date	Comments
10/14/08	Replace policy - Policy updated with literature search; no change to the policy statement. Codes 37.52-37.66 added, references added.
10/13/09	Replace policy - Policy updated with literature search; no change to the policy statement. References added.
02/09/10	Codes Update - New 2010 codes added.
11/09/10	Replace policy - Policy updated with literature search; references 1, 10, 19, 29 and 30 added. Extensive editing completed. Policy statements revised to address only implantable VADs and total artificial hearts.
10/11/11	Replace policy – Policy updated with literature search. Percutaneous VADs, previously not addressed, added to policy statement as investigational. Rationale updated. References 22, 30-39, 42, 43 added. ICD-10 codes added to policy.
11/27/12	Replace policy - Policy updated with literature search. References 18, 27-31, 33, 40, 47. Clause added to policy statement on TAH that says "...or are undergoing evaluation to determine candidacy for heart transplantation..."
01/10/13	Coding update. CPT codes 0148T – 0150T deleted as of 12/31/12; codes 33990 – 33991 and 33993, effective 1/1/13, added to policy.
04/08/13	Replace policy. Policy 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. Code Q0505, deleted 3/13/13; this is replaced with Q0507-Q0509, new codes 4/1/13.
03/11/14	Coding Update. Codes 37.52 - 37.55, 37.55, 37.60, and 37.62 - 37.66 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.
07/31/14	Annual Review. Policy updated with literature review through January, 2014 and results of clinical vetting related to the use of pVADs and the total artificial heart (TAH) as destination therapy. References 5, 6, 20, 23, 24, 27, 55 added; others renumbered/removed. Policy statements unchanged.
07/14/15	Annual Review. Policy updated with literature review through April 21, 2015; references 7-8, 27, 32, 38, 41, 50, 55, 57, 61-62, 65-66, and 70 added. Policy statements unchanged. Coding update: CPT codes 33977, 33978, 33980, 33981, 33982, 33983 and 93750, plus HCPCS Q0506 removed; they were informational only.
11/01/16	Annual Review, approved October 11, 2016. Policy revised to remove all information regarding total artificial hearts and -implantable ventricular assist devices, including removing previous references 1-56 and policy title change. Policy now addresses only percutaneous ventricular assist devices. Policy updated with literature review but no change to the policy statement regarding pVADs, which remain investigational.
11/01/17	Annual review approved October 10, 2017. Policy updated with literature review through July 22, 2017; references 5-7, 34, 47, 49-51, 70, 72, 83, 85, 88, and 93 added. Policy statements revised to add information regarding total artificial hearts and



Date	Comments
	implantable ventricular assist devices. Codes updated; removed 33999 and added 0051T, 0052T, and 0053T.
03/03/18	Coding update; added note that CPT codes 0051T, 0052T, and 0053T were terminated 1/1/18. Added new CPT codes 33927, 33928, and 33929 (new codes effective 1/1/18).
11/01/18	Annual Review, approved October 26, 2018. Policy updated with literature review through June 2018; several references added. Other than minor editing for clarity, policy statements unchanged. Added CPT codes 33975, 33976, 33979, 33981, 33982, 33983.
01/01/19	Coding update, removed CPT codes 0051T, 0052T, and 0053T as they were terminated 1/1/18.
11/01/19	Annual Review, approved October 4, 2019. Policy updated with literature review through June 2019; references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
05/06/20	Interim Review, approved May 5, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
07/02/2020	Coding update. Removed CPT's 33981, 33982, 33983, 33990, 33991, 33992, 33993.
11/01/20	Annual Review, approved October 22, 2020. Policy updated with literature review through June 2020; references added. Policy statements unchanged. Added codes 33981, 33982, 33983, 33990, 33991, 33992, 33993.
12/01/20	Coding update, added new CPT codes 33995 & 33997 effective 1/1/2021.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.



Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

አማርኛ (Amharic):

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀዳሾች ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰብሰብ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحتوي هذا الإشعار على معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):

Beeksisni kun odeeffannoo barbaachisaa qaba. Beeksisni kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

Français (French):

Cet avis a d'importantes informations. Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnu ntawm Premera Blue Cross. Tej zaum muaj cov hnu tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas pab kom koj ua tsis pub dhau cov caij nyuog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenna coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenna tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កំណត់ថ្លៃជាតំបន់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអន្តរជាតិរបស់អ្នក ឬប្រាក់ដុល្លារចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਕੱਠ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).