

MEDICAL POLICY – 7.03.11

Total Artificial Hearts and Implantable Ventricular Assist Devices

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RELATED MEDICAL POLICIES:

None

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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)	<p>FDA approved ventricular assist devices (VADs) may be considered medically necessary as a bridge to heart transplantation for adult and pediatric 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 or clearance	<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: <ul style="list-style-type: none"> New York Heart Association class IV heart failure for ≥ 60 days,



Device	Medical Necessity
	<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> <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 or clearance – 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

- 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



Documentation Requirements

- 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
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 transseptal puncture



Code	Description
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
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)

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

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.

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.

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.



Description

A ventricular assist device (VAD) is a 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 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 1 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 left ventricle, pulmonary artery for the right ventricle). A small portion of the ventricular wall is removed for insertion of the outflow tube; extensive cardiomy 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 2 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. 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 IABP for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates associated with pVAD use. Another randomized controlled trial comparing pVAD with IABP as an adjunct to high-risk percutaneous coronary interventions was terminated early due to futility; analysis of enrolled subjects did not demonstrate significant improvements in the pVAD group. 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 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			
NCT01774656^a	Remission From Stage D Heart Failure (RESTAGE-HF)	40	Dec 2017 (ongoing)
NCT01627821^a	Evaluation of the Jarvik 2000 Left Ventricular Assist System With Post-Auricular Connector--Destination Therapy Study	350	Dec 2018
NCT01369407	REVIVE-IT Registry (REVIVAL: Registry Evaluation of Vital Information For VADs in Ambulatory Life)	400	Jun 2019
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 2020
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	20	Dec 2021
NCT02387112	Early Versus Emergency Left Ventricular Assist Device Implantation in Patients Awaiting Cardiac Transplantation	500	Dec 2022
NCT02459054	SynCardia 50cc Temporary Total Artificial Heart (TAH-t) as a Bridge to Transplant	72	Jun 2024
Unpublished			
NCT02468778	Supporting Patients Undergoing HIgh-Risk PCI Using a High-Flow PErcutaneous Left Ventricular Support Device (SHIELD II)	425	Jan 2018 (suspended)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Clinical Input Received 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 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

Society for Cardiovascular Angiography and Interventions et al

The Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America, the Society of Thoracic Surgeons, and the American College of Cardiology (2015) published a joint clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care.⁷⁹ 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.



The American College of Cardiology Foundation et al

The American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of America (2017) 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 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.⁸¹ The guidelines categorized percutaneous ventricular assist devices (pVADs) and extracorporeal VADs as nondurable MCS devices. **Table 2** provides class IIA guidelines on MCS devices.

Table 2. 2013 Guidelines on 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 (2012) published recommendations for the use of MCS.⁸² These guidelines defined nondurable MCS as intraballoon pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. **Table 3** lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 3. 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
"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	IIA	B



Recommendation	COE	LOE
MCS.”		

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)

The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure.⁸³ **Table 4** lists recommendations on left VADs:

Table 4. 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.

Medicare National Coverage

Medicare has a national coverage determination (NCD) for artificial hearts and related devices, including VADS.⁸⁴ 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 and listed as a candidate 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 5](#) and [Table 6](#).

Table 5. 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
CentriMag®	Levitronix (now Thoratec)	Oct 2008	HDE	H070004	Postcardiotomy
Berlin Heart EXCOR® Pediatric VAD	Berlin	Dec 2011	HDE	H100004	Bridge to transplant
HeartWare® Ventricular Assist System	HeartWare	Dec 2012	PMA	P100047	Bridge to transplant
HeartMate 3™ Left Ventricular Assist System	Thoratec	Aug 2017	PMA	P160054	Bridge to transplant and 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 FDA through the premarket approval process as a bridge to transplantation in patients suffering from 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 for 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 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
- Are not weanable from biventricular support if on such support.

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

Percutaneous VADs (Circulatory Assist Devices)

Table 6. 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 2 randomized controlled trials of 2 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 in August 2017 but was recalled in April 2018. 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.⁶⁻¹⁰ 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.

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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



Date	Comments
	statement unchanged; total artificial hearts are investigational. References added.
12/11/06	Codes Updated - No other changes
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



Date	Comments
	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 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.

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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 ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታወቅ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار 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 hns ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog 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-ato 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 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. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາອ້ອງສະໝັກ 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 ដល់កិច្ចការច្នៃផ្ទះធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ដុល្លារចេញផ្លូវ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ 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 ਇਛੁੱਕ 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).