BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Total Artificial Hearts and Related Devices

Policy #: 033
Category: Surgery

Latest Review Date: April 2021
Policy Grade: A

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

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POLICY:

Effective for dates of service on or after December 1, 2020:

For percutaneous ventricular assist devices, refer to Articles A53986 and A53988.

For ventricular assist devices, refer to NCD 20.9.1.

Blue Advantage will treat **total artificial hearts with FDA-approved devices** as a **covered benefit** when performed in a Medicare-approved heart transplant facility as a bridge to heart transplantation when ALL of the following criteria are met:

- Biventricular failure AND,
- No other reasonable medical or surgical treatment options; AND
- Are ineligible for other univentricular or biventricular support devices; AND
- Are currently listed as heart transplantation candidates

OR

- Are undergoing evaluation to determine candidacy for heart transplantation; AND
- Are not expected to survive until a donor heart can be obtained.

Blue Advantage will treat **total artificial hearts** as a **non-covered benefit** and **investigational** for all other indications, including, but not limited to, the use of total artificial hearts as destination therapy.

For dates of service February 26, 2018 through November 30, 2020:

For artificial hearts and related devices refer to NCD 20.9.
For percutaneous ventricular assist devices, refer to Articles A53986 & A53988.
For ventricular assist devices refer to NCD 20.9.1.

For dates of service prior to February 26, 2018:

For artificial hearts and related devices refer to NCD 20.9.
For ventricular assist devices refer to NCD 20.9.1

Blue Advantage will treat **percutaneous ventricular assist devices (pVAD)** with FDA approval or clearance as as a **covered benefit** for use in patients **undergoing high risk percutaneous coronary intervention (PCI)** when **All** of the following are met:

- Patient has LVEF of less than 35% **AND;**
- Will undergo PCI on an unprotected left main coronary artery or last patent coronary conduit.

Blue Advantage will treat **percutaneous ventricular assist devices (pVAD)** as a **non-covered benefit** and **investigational** for all other indications**.**

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Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Mechanical devices to assist or replace a failing heart have been developed over many decades of research. 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 who are not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

Heart Failure

Heart failure may be the consequence of a number of differing 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. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

Treatment

Total Artificial Heart (TAH)

Initial research into mechanical assistance for the heart focused on the total artificial heart, a biventricular device which completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems utilize 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 electrohydrolically actuated, has been developed and tested in 2 patients, but is currently experimental.

Percutaneous Ventricular Assist Devices (pVADs)

Devices in which the majority of the system's components are external to the body are for short-term use (six 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, (i.e., are not implanted). These may be referred to as percutaneous VADs (pVADs). The pVADs are 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 that is 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 (MI), stroke, and arrhythmias.

KEY POINTS:

The most recent literature search was performed for the period through April 12, 2021.

Summary of Evidence

Total Artificial Heart

For individuals who have end stage heart failure who receive total artificial hearts (TAHs) as bridge to transplant, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, treatment-related mortality, and treatment-related morbidity. Compared with VADs, the evidence for total artificial heart in these settings is less robust. However, given the limited evidence from case series and the lack of medical or surgical options for these patients, 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 an LVAD. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end stage heart failure who receive TAHs as destination therapy, the evidence includes 2 case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, treatment-related mortality, and treatment-related morbidity. The body of evidence for TAHs as destination therapy is very limited. 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 RCTs, observational studies, and systematic reviews. The relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD vs IABP for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies were consistent with the RCT evidence. RCTs, controlled and uncontrolled observational studies, and systematic reviews of these studies have not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cardiogenic shock refractory to IABP therapy who receive a pVAD, the evidence includes case series. The relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to 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.

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

Table 1. 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.

Society for Cardiovascular Angiography and Interventions et al

In 2015, the Society for Cardiovascular Angiography and Interventions (SCAI), the Heart Failure Society of America (HFSA), the Society of Thoracic Surgeons (STS), the American Heart Association (AHA), and the American College of Cardiology (ACC) published a clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care. This statement addressed intra-aortic balloon pumps (IABPs), left atrial (LA)-to-aorta assist device (e.g., TandemHeart®), left ventricle (LV)-to-aorta assist devices (e.g., Impella®), extracorporeal membrane oxygenation (ECMO), 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:

1. "Percutaneous MCS provides superior hemodynamic support compared to pharmacologic therapy. This is particularly apparent for the Impella® and TandemHeart® devices. These devices should remain available clinically and be appropriately reimbursed.
2. Patients in cardiogenic shock represent an extremely high risk group in whom mortality has remained high despite revascularization and pharmacologic therapies. Early placement of an

appropriate MCS may be considered in those who fail to stabilize or show signs of improvement quickly after initial interventions.
3. MCS may be considered for patients undergoing high-risk PCI, such as those requiring multivessel, left main, or last patent conduit interventions, particularly if the patient is inoperable or has severely decreased ejection fraction or elevated cardiac filling pressures."

American College of Cardiology Foundation et al
The American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of American (2017) published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA. 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. The guidelines categorized percutaneous ventricular assist devices (pVADs) and extracorporeal VADs as nondurable MCS devices.

American College of Cardiology and American Heart Association
The American College of Cardiology and American Heart Association (ACC/AHA) released guidelines for the management of heart failure in October 2013 that include recommendations related to the use of for mechanical circulatory support (MCS), including both durable and nondurable MCS devices. The guidelines categorize pVADs and extracorporeal VADs as nondurable MCS devices. The following class IIA guidelines are made related to MCS devices:

- MCS is beneficial in carefully selected patients with stage D heart failure with reduced ejection fraction (HFrEF) in whom definitive management (e.g., cardiac transplantation) or cardiac recovery is anticipated or planned. (Level of Evidence: B)
- Nondurable MCS, including the use of percutaneous and extracorporeal VADs, is reasonable as a "bridge to recovery" or "bridge to decision" for carefully selected patients with HFrEF with acute, profound hemodynamic compromise. (Level of Evidence; B)
- Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HFrEF. (Level of Evidence: B)

The AHA/ACC guidelines note:
"Although optimal patient selection for MCS remains an active area of investigation, general indications for referral for MCS therapy include patients with LVEF <25% and NYHA Class III–IV functional status despite GDMT, including, when indicated, CRT, with either high predicted one to two year mortality (e.g., 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 and transplantation cardiologists, cardiothoracic surgeons, nurses, and ideally, social workers and palliative care clinicians."

In 2012, AHA published recommendations for the use of MCS. These guidelines define nondurable MCS as intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. The following recommendations were made regarding indications for use of MCS, including durable and nondurable devices:

- MCS for bridge-to-transplant indication should be considered for transplant-eligible patients with end-stage heart failure who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation. (Class I; Level of Evidence B).
- Implantation of MCS in patients before the development of advanced heart failure… is associated with better outcomes. Therefore, early referral of heart failure patients is reasonable. (Class IIa; Level of Evidence B).
- MCS with a durable, implantable device for permanent therapy or destination therapy is beneficial for patients with advanced heart failure, high one year mortality resulting from heart failure, 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. (Class I; Level of Evidence B).
- Elective rather than urgent implantation of destination therapy can be beneficial when performed after optimization of medical therapy in advanced heart failure patients who are failing medical, surgical, and/or device therapies. (Class IIa; Level of Evidence C).
- Urgent nondurable MCS is reasonable in hemodynamically compromised heart failure 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. (Class IIa; Level of Evidence C).
- These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced heart failure. (Class I; Level of Evidence C).
- Patients who are ineligible for heart transplantation because of pulmonary hypertension related to heart failure alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS. (Class IIa; Level of Evidence B).

Heart Failure Society of America

The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure. The following recommendations were made regarding left ventricular assist devices:

- 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. (Strength of Evidence = B)
- Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF [heart failure] 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. (Strength of Evidence = 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. (Strength of Evidence = C)

U.S. Preventive Services Task Force Recommendations
Not applicable

KEY WORDS:

Ventricular assist device, biventricular support, BIVAD, cardiac support, heart transplantation (transplant), LVAD, VAD, destination therapy, HeartWare®, Impella LV®, Impella 2.5, Impella 2.5 circulatory assist device, DeBakey, percutaneous ventricular assist device, pVAD, TandemHeart®, Berlin Heart EXCOR®, Impella RP, Carmat, bioprosthetic artificial heart, HeartMate III™, Total Artificial Heart, TAH, CardioWest™ Total Artificial Heart, HeartMate II®, SynCardia artificial heart, Right Ventricular Assist Device, RVAD, PediMag®, short-term continuous flow ventricular assist devices, STCF-VADs, intraluminal axial support, HeartAssist 5 Pediatric Ventricular Assist Device; NuPulseCV iVAS; Symphony Heart Assist System; CentriMag® Blood Pump; Implantable Aortic Counterpulsation Ventricular Assist Devices; Intravascular Ventricular Assist Systems; iVAS); C-Pulse, CardioVAD

APPROVED BY GOVERNING BODIES:

A number of mechanical circulatory support devices have received approval or clearance for marketing by FDA. These devices are summarized in Table 2, and described further in the sections below.

Table 2: Available Mechanical Circulatory Support Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
Thoratec® IVAD	Thoratec	Aug 2004	PMA supplement	P870072	Bridge to transplant and postcardiotomy
DeBakey VAD®	MicroMed	Feb 2004	HDE	H030003	Bridge to transplant in children 5-16 years of

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Child					age
HeartMate II®	Thoratec	Apr 2008	PMA	P060040	Bridge to transplant and destination therapy
Centrimag®	Levitronix	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, and destination therapy
HeartMate III™ Left Ventricular Assist System	Thoratec	Aug 2017	PMA	P160054 P160054/S008	Bridge to transplant, and destination therapy

FDA: Food and Drug Administration; HDE: humanitarian device exemption; PMA: premarket approval

Ventricular Assist Devices

In December 1995, the Thoratec® Ventricular Assist Device System (Thoratec Corp., Pleasanton, CA) was approved by the FDA through the premarket approval process for use 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 May 1998, supplemental approval for the above device was given for the indication for postcardiotomy patients who are 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 in the company of a trained caregiver. In November 2003, supplemental approval was given to market the device as Thoratec® Paracorporeal VAD. In August 2004, supplemental approval was given to a modified device to be marketed as the

Thoratec® Implantable VAD for the same indications. In January 2008, supplemental approval was given to delete Paracorporeal VAD use.

In February 2004, the FDA approved the DeBakey VAD® Child under the HDE approval process. According to the FDA, this device is indicated under HDE for both home and hospital use for children who are between ages 5 and 16 years and who have end-stage ventricular failure requiring temporary mechanical blood circulation until a heart transplant is performed.
In April 2008, continuous flow device HeartMate II® LVAS (Thoratec, Pleasanton, CA) was approved by the FDA through the premarket approval process for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The Heartmate II® LVAS is intended for use both inside and outside the hospital. In January 2010, the device received the added indication as destination therapy for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days and are not candidates for cardiac transplantation.

In October 2008, device Centrimag® Right Ventricular Assist Device (Levitronix, Zurich) was approved by the FDA under the HDE to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right-sided heart failure.

In December 2011, the Berlin Heart EXCOR® Pediatric VAD was approved via HDE. The indications for this device are pediatric patients with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

In December 2012, device HeartWare® Ventricular Assist System (HeartWare, Inc., Framingham, Mass.) was approved by the FDA using the INTERMACS registry as a control. INTERMACS registry was established in 2005 as a joint effort involving the FDA, National Heart, Lung and Blood Institute (NHLBI), Centers for Medicare and Medicaid Services (CMS), clinicians, scientists, and industry. This was the first time the FDA approved an LVAD using registry data as a control. INTERMACS is managed by the University of Alabama at Birmingham.

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.

In September 2017, HeartWare® Ventricular Assist System (HeartWare, Inc., Framingham, Mass.) was approved by the FDA for providing long-term hemodynamic support (e.g., destination therapy) in patients with advanced heart failure.

In August 2017, the HeartMate™ 3 Left Ventricular Assist System (Thoratec Corp., Pleasanton, CA) was approved by the FDA for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.

In October 2018, the HeartMate™ 3 Left Ventricular Assist System (Thoratec Corp., Pleasanton, CA) was approved by the FDA for providing long-term hemodynamic support (e.g., destination therapy) in patients with advanced heart failure.

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 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 FDA through the humanitarian device exemption (H040006) process in severe biventricular end-stage heart disease patients who are not cardiac transplant candidates and who:

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

In addition to meeting other criteria, patients who are candidates for the AbioCor® 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 about 90% of women and for many men.

****NOTE: The Carmat bioprosthetic total artificial heart has not been FDA approved.**

Percutaneous VADs (Circulatory Assist Devices)
Table 3. 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	Abiomed	Mar	PMA	P140003	Temporary ventricular

System		2015			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. The MOMENTUM 3 trial compared HeartMate III™ 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 III™ 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. 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.

Percutaneous Ventricular Assist Devices (circulatory assist devices)

The Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Aachen, Germany) received FDA 510(k) approval in May 2008 for short-term (less than six hours) use in patients requiring circulatory support.

In March 2015, the Impella® 2.5 System received approval through the PMA process for temporary ventricular support during high-risk percutaneous coronary interventions.
The TandemHeart® (Cardiac Assist, Pittsburgh) received a similar 510(k) approval for short-term circulatory support in September 2005.

Several other devices are in clinical trials or awaiting FDA review.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT codes:

33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy (Effective 01/01/18)
33928	Removal and replacement of total replacement heart system (artificial heart) (Effective 01/01/18)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure) (Effective 01/01/18)
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only (Revised 01/01/21)
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture (Revised 01/01/21)
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion (Revised 01/01/21)
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion (Revised 01/01/21
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only (Effective 01/01/21)
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion (Effective 01/01/21)

HCPCS Codes:

L8698	Miscellaneous component, supply or accessory for use with total artificial heart system (Effective 01/01/2019)

PREVIOUS CODING:

0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy (Deleted 12/31/17)
0052T	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart) (Deleted 12/31/17)
0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit (Deleted 12/31/17)

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POLICY HISTORY:

Adopted for Blue Advantage, February 2016
Available for comment February 15 through March 30, 2016
Medical Policy Group, August 2016
Medical Policy Group, September 2017
Medical Policy Group, February 2018
Medical Policy Group, September 2020
Medical Policy Group, November 2020: Annual Coding Update. Added new CPT codes 33995 and 33997. Revised CPT codes 33990-33993 to clarify left or right heart.
Medical Policy Group, April 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.