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Medical Policy

Subject:	Mechanical Circulatory Assist Devices (Ventricular Assist Devices, Percutaneous Ventricular Assist Devices and Artificial Hearts)		
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Description/Scope

This document addresses mechanical circulatory support and artificial heart systems. Devices include the following:

- Ventricular assist devices (VADs), a mechanical pump used to help hearts that can no longer pump blood effectively due to heart failure. Ventricular assist devices may be used as a bridge to transplantation or as a permanent alternative to heart transplantation.
- Percutaneous ventricular assist devices (pVADs), also known as circulatory assist devices are small mechanical pumps typically inserted through a femoral artery with the proposed use as a short-term bridge to recovery.
- Total artificial heart, a pulsating bi-ventricular device that is implanted into the chest to replace the individual's left and right ventricles. The total artificial heart provides a bridge to transplantation for individuals who have no other reasonable medical or surgical treatment options.

Note: This document does not address the *percutaneous intra-aortic balloon assist pump (IABP).*

Note: Please see the following related document for additional information:

- TRANS.00033 Heart Transplantation

Position Statement

I. *Ventricular Assist Devices (VADs) including Left, Right and Biventricular Assist Devices (Adult)*

Medically Necessary:

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~~Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.~~

A. U.S. Food and Drug Administration (FDA) approved ventricular assist devices (VADs)*, used in accordance with FDA approval, are considered **medically necessary** as a *bridge to heart transplant* for individuals when **all** of the following criteria have been met:
   1. Have severe end stage heart failure; **and**
   2. Are not expected to survive until a donor heart can be obtained; **and**
   3. When **one** of the following criteria has been met:
      a. Currently listed as a heart transplant candidate; **or**
      b. Undergoing evaluation to determine candidacy for heart transplant.

B. FDA approved VADs*, used in accordance with FDA approval, are considered **medically necessary** in the *post-cardiotomy setting* as a means of myocardial recovery support for individuals who are unable to be weaned off cardiopulmonary bypass.

C. FDA approved VADs*, used in accordance with FDA approval, are considered **medically necessary** when used as a *permanent alternative (destination therapy)* to heart transplantation for an individual when **all** of the following criteria have been met:
   1. Was evaluated and determined not to be eligible for a heart transplant; **and**
   2. Has documented Class III or IV New York Heart Association (NYHA) end stage left ventricular heart failure; **and**
   3. Has received optimal medical management, for at least 45~~60~~ of the last 60~~90~~ days or the individual's survival is in jeopardy; **and**
   4. Has a life expectancy of less than 2 years due to heart disease.

***Note:** Please refer to the background section of the document for a list of FDA approved VADs.

Investigational and Not Medically Necessary:

Ventricular assist devices are considered **investigational and not medically necessary** for all other conditions not listed above.

Use of a non-FDA approved or cleared ventricular assist device is considered **investigational and not medically necessary.**

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II. ***Ventricular Assist Devices (Pediatric)***

Medically Necessary:

A. FDA approved VADs appropriate for pediatrics, including humanitarian device approvals, used in accordance with FDA approval, are considered **medically necessary** for use in children when **all** of the following criteria have been met:

1. Child has documented end-stage left ventricular failure; **and**
2. ~~A~~ Pediatric appropriate VAD* (based on FDA approved use) will be used; and meets either criteria (a) or (b) below:
   a. ~~u~~Until a donor heart can be obtained; **or**
   ~~2.~~b. When used as a *permanent alternative (destination therapy)* in children who have been evaluated and determined not to be eligible for a heart transplant.

*Current FDA approved ventricular assist devices appropriate for pediatrics:

a. Child under age 5: the Berlin Heart EXCOR® Pediatric Ventricular Assist Device; **or**
b. Child between ages 5 and 16: either the HeartAssist®5 Pediatric Ventricular Assist Device or the Berlin Heart EXCOR Pediatric Ventricular Assist Device; **or**
c. Child with body surface area (BSA) greater than or equal to 1.0~~2~~ meter squared (m^2): The HeartMate™ 3 Left Ventricular Assist System (FDA approved as bridge to transplant **or** *destination therapy* without a specific age requirement and this may be used in pediatric populations).
~~c.~~

Not Medically Necessary:

Pediatric VADs are considered **not medically necessary** in children when all the criteria specified above are not met, or when any of the following contraindications are present:

A. Have right ventricular failure; **or**
B. Have a blood-clotting (primary coagulopathy) or platelet disorder such as hemophilia or Von Willebrand's disease; **or**

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C. Have a known allergy or sensitivity to the blood thinner heparin; **or**
D. Have anatomical anomalies that would prevent surgical connection of the outflow graft to the ascending aorta.

Investigational and Not Medically Necessary:

Pediatric VADs are considered **investigational and not medically necessary** for all other conditions not listed above.

Use of a non-FDA approved or cleared VAD is considered **investigational and not medically necessary.**

III. *Percutaneous Ventricular Assist Devices (pVADs)*

Medically Necessary:

FDA approved pVADs*, used in accordance with FDA approval are considered **medically necessary** for the treatment of individuals with *cardiogenic shock* when the following criteria are met:
A. Treatment is intended as an alternative to extracorporeal membrane oxygenation (ECMO); **or**
B. Optimal medical management and conventional treatment measures (that is, volume loading and use of pressors and inotropes) has failed to provide sufficient improvement; **and**
C. Individual is suspected to have a reversible cardiac injury and does not have irreversible end-organ injury including renal, hepatic or neurologic systems (care is not felt to be futile).

***Note:** Please refer to the background section of the document for a list of FDA approved pVADs.

Investigational and Not Medically Necessary:

The use of pVADs is considered **investigational and not medically necessary** when the above criteria are not met, and for all other indications.

IV. *Artificial Heart Systems*

Medically Necessary:

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The SynCardia temporary Total Artificial Heart (TAH-t), used in accordance with FDA approval, is considered **medically necessary** as a bridge to heart transplantation for individuals who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and who meet **all** of the following criteria:

A. Eligible for heart transplantation; **and**
B. Listed for heart transplantation and in imminent danger of dying within 48 hours or becoming ineligible for transplant; **and**
C. NYHA Functional Class IV; **and**
D. Presence of biventricular failure and rapid decompensation; **and**
E. Unavailability of heart donor and likelihood that condition will deteriorate before donor can be identified; **and**
F. Body surface area 1.7-2.5 m^2*, **or** have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) greater than or equal to 10 cm (See asterisk below for factors that may allow an exception to this criteria.); **and**
G. Absence of active systemic infection; **and**
H. Absence of irreversible organ dysfunction; **and**
I. Serum Creatinine less than 5 mg/dl; **and**
J. Total Bilirubin less than 5 mg/dl; **and**
K. Cytotoxic antibody level less than 10%; **and**
L. Pulmonary Vascular Resistance less than 8 Wood units; **and**
M. Unresponsive to optimal medical therapy; **and**
N. Presence of hemodynamic insufficiency demonstrated by either of the following:
    1. Cardiac index less than or equal to 2 L/min/M^2 and **one** of the following:
        a. Systolic arterial pressure less than or equal to 90 mm Hg;
        b. Central venous pressure greater than or equal to 18 mm Hg.

        or
    2. **Two** of the following:
        a. Dopamine greater than or equal to 10 µg/kg/min; **or**
        b. Dobutamine greater than or equal to 10 µg/kg/min; **or**
        c. Epinephrine greater than or equal to 2 µg/kg/min; **or**
        d. Isoproterenol greater than or equal to 2 µg/kg/min; **or**
        e. Amrinone greater than or equal to 10 µg/kg/min; **or**

f. Other cardioactive drugs at maximal doses; **or**
g. IABP; **or**
h. Failure to wean from cardiopulmonary bypass (CPB).

Not Medically Necessary:

The SynCardia temporary Total Artificial Heart (TAH-t) is contraindicated and considered **not medically necessary** in individuals who meet **any one** of the following:

1. Individuals who are not cardiac transplant eligible; **or**
2. Individuals who do not have sufficient space in the chest area vacated by the native ventricles*. Generally this includes individuals who have body surface areas less than 1.7 m^2, or who have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) less than 10 cm. (See asterisk below for additional information.)*; **or**
3. Individuals who cannot be adequately anticoagulated on the SynCardia TAH-t; **or**
4. Individuals with end-stage, irreversible organ dysfunction other than heart.

Investigational and Not Medically Necessary:

The SynCardia temporary Total Artificial Heart (TAH-t) is considered **investigational and not medically necessary** for all other conditions not listed above.

Use of a non-FDA approved or cleared heart replacement system is considered **investigational and not medically necessary.**

The AbioCor® Implantable Replacement Heart System is considered **investigational and not medically necessary** for all indications.

***Note:** The proper functioning of the implanted SynCardia TAH-t can be impaired in smaller individuals, that is, those with a body surface area of less than 1.7 m^2 and a heart size less than or equal to 1500 cc, or whose anteroposterior diameter from the sternum inner table to the anterior vertebral body is less than 10 cm. In these cases, the implanted device may compress the inferior vena cava or the pulmonary veins. If an individual has a body size area less than 1.7 m^2, implantation of a TAH may still be possible if the presence of cardiomegaly allows for sufficient space for device placement.

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Note: In general age greater than or equal to 18 years and less than or equal to 59 years is a relative indication.

Rationale

Ventricular Assist Devices

Based on current peer review literature, the durable VAD is shown to significantly improve health outcomes when used as a bridge to transplant, for bridge to recovery in the post-cardiotomy individual, or as a permanent alternative to heart transplantation when specified criteria are met.

The 2009 American College of Cardiology/American Heart Association (ACC/AHA) Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult included reference to consideration of a left ventricular assist device as permanent or "Destination Therapy" as being reasonable in highly selected individuals with refractory end-stage heart failure and an estimated 1-year mortality of over 50% with medical therapy. The ACC/AHA document added that use of mechanical circulatory assist devices for short-term circulatory support in individuals who are expected to recover from a major cardiac insult is an area of intense investigation. Most clinical experience currently available with these devices has been derived from their use in individuals being "bridged" to transplant (Hunt, 2009).

The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial investigated the use of these devices as permanent or "Destination Therapy" in selected non-transplant-eligible subjects. According to authors the REMATCH analyses included 129 enrolled subjects, for whom 2-year survival was 23% in the 68 subjects treated with devices (HeartMate® XVE LVAS Thoratec, CORP, Pleasanton, CA) and 8% in the 61 subjects who received medical therapy. Device-related adverse events were numerous and included bleeding, infection, thromboembolic events, and device failure. This trial established the efficacy of device therapy for end-stage heart failure. According to the ACC/AHA updated guideline, destination device therapy is anticipated to benefit those individuals predicted to have a 1-year survival of less than 50%. One such group could be the population of non-transplant-eligible subjects requiring continuous intravenous inotropic infusions (Hunt, 2009).

Findings from other studies evaluated the use of implantable VADs as a bridge to transplantation. These studies indicated that use of these devices can improve functional and hemodynamic status and is associated with higher survival rates, compared with optimal medical therapy. The positive effect of these devices on post-heart transplant

survival can be attributed, in part, to the efficient circulatory support provided by these devices and to the fact that transplant candidates who have been stabilized by these devices can wait for an optimal and well-matched organ and, therefore, are more likely to have a successful outcome (Aaronson, 2002; Frazier, 2001; Holman, 2002; Morgan, 2004; Vitali, 2003). Additional studies are currently underway that are examining different types of VADs and new power sources, in addition to evaluations of specific clinical indications for use of these devices.

In November 2012, the FDA approved a small, continuous-flow centrifugal pump known as the HeartWare® Ventricular Assist Device (HVAD) System (HeartWare, Inc., Framingham, MA) as a bridge to cardiac transplantation in candidates at risk for death from end-stage heart failure that was unmanageable by standard medical therapy. The approval was based on results from a multicenter prospective study comparing the HVAD device to that of currently available FDA approved VADs used as a bridge to cardiac transplantation. Aaronson and colleagues (2012) reported the primary outcome results; success as defined by survival for at least 180 days on original pump or transplantation, occurred for 90.7% of the HVAD population and 90.1% of the control population, establishing the non-inferiority of the HVAD pump ($p<0.001$; 15% non-inferiority margin). Survival outcomes for the HVAD were reported at 99% for 30 days, 94% at 180 days and 86% at 1 year and 97%, 90% and 85% for the control group. The authors concluded use of the HVAD:

> Was associated with high rates of 180-day success and survival and a favorable adverse event profile when used as a bridge to transplantation. Perioperative mortality was 1%, and survival at 1 year was 86%. Quality-of-life and functional capacity improvements were much larger than those seen with any drug or device therapy for advanced heart failure and were similar to those obtained with cardiac transplantation.

In August 2017, the FDA granted premarket approval (PMA) of the HeartMate™ 3 Left Ventricular Assist System (LVAS) (Abbott Cardiovascular, Plymouth, MN) for short-term hemodynamic support (that is bridge to transplant or bridge to myocardial recovery) in individuals who have advanced refractory left ventricular heart failure. On October 18, 2018, the FDA expanded approval of the HeartMate 3 LVAS for long-term mechanical support (destination therapy) for end stage left sided heart failure. The FDA approval is based on safety and effectiveness data from the MOMENTUM 3 trial, a randomized noninferiority and superiority trial in 366 participants that compared the HeartMate 3 LVAS, a centrifugal-flow pump (n=190), with the HeartMate II Left Ventricular Assist Device (LVAD), an axial-flow pump (n=176), in the treatment of advanced heart failure, irrespective of the intended goal of support (bridge to transplantation or destination therapy) (Mehra, 2018). In the intention-to-treat population, the primary end point occurred in 79.5% (n=151) of the HeartMate 3 LVAS population and 60.2%

(n=106) of the HeartMate II LVAD population (absolute difference, 19.2 percent points; 95% lower confidence boundary, 9.8 percentage points [p<0.001 for superiority]). Reoperation for pump malfunction was less frequent in the HeartMate 3 LVAS group (1.6%; 3 participants) than in the HeartMate II LVAD group (17.0%; 30 participants) (hazard ratio, 0.08; 95% CI, 0.03 to 0.27; p<0.001). Among the two groups, the rates of disabling stroke were similar, but the overall rate of stroke was lower in the HeartMate 3 LVAS group than in the HeartMate II LVAD group (10.1% versus 19.2%; HR, 0.47; 95% CI, 0.27 to 0.84, p=0.02). Mehra and colleagues concluded that "in patients with advanced heart failure, a fully magnetically levitated centrifugal-flow pump was superior to a mechanical-bearing axial-flow pump with regard to survival free of disabling stroke or reoperation to replace or remove a malfunctioning device".

The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guideline for the management of HF, provides guidance on "Guideline-directed medical therapy" (GDMT) (also known as optimal medical management). Current HF guidelines consider *refractory* HF when an individual has failed GDMT (appropriate intravenous medications, mechanical circulatory support [MCS] or oxygen therapy).

In 2019, Mehra and colleagues reported findings from the MOMENTUM 3 trial which included 1028 advanced heart failure participants that were randomly assigned to the centrifugal-flow HeartMate 3 LVAS group (n=516) or the axial-flow HeartMate II LVAS group (n=512), irrespective of the intended goal of use (bridge to transplantation or destination therapy). In the analysis of the primary endpoint, 76.9% of participants (n=397) in the HeartMate3 LVAS group compared to 64.8% (n=332) in the HeartMate II group remained alive and free of disabling stroke or reoperation to replace or remove a malfunctioning device at 2 years (relative risk, 0.84; 95% CI, 0.78 to 0.91; p<0.001 for superiority). There were fewer pump replacements in the HeartMate 3 LVAS group than in the HeartMate II group (2.3% [n=12 participants] versus 11.3%, [n=57 participants]) (relative risk, 0.21; 95% CI, 0.11 to 0.38; p<0.001). "The numbers of events per patient-year for stroke of any severity, major bleeding, and gastrointestinal hemorrhage were lower in the centrifugal-flow pump group than in the axial-flow pump group." The authors concluded that:

> The centrifugal-flow HeartMate3 left ventricular assist device was associated with a less frequent need for pump replacement than the axial-flow HeartMate II left ventricular assist device and was superior to the axial-flow pump with respect to survival free of disabling stroke or reoperation to replace or remove a malfunctioning device.

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Goldstein and colleagues (2020) reported prespecified secondary analysis from the MOMENTUM 3 trial (NCT02224755), a multicenter randomized clinical trial that compared the HeartMate 3 to the HeartMate II. Participants with advanced HF were randomized to an LVAD, irrespective of the goal of supported therapy (bridge to transplant [BTT] group, bridge to candidacy [BTC] group versus destination therapy [DT] group). The primary outcome results; survival free of disabling stroke or reoperation to remove or replace a malfunction device at 2 years, HeartMate 3 was superior to HeartMate II use in participants with BTT/BTC group (76.8% vs 67.3%; HR, 0.62 [95% CI, 0.40-0.94]; log-rank p=0.2) and participants in the DT group (73.2% vs 58.7%; HR, 0.61 [95% CI, 0.46-0.81]; log-rank p<0.001). There was not a significant difference in reduction of adverse events reported between the two pumps. The improvement in QOL and functional for either pump were not significantly different irrespective of the treatment strategy. In summary, the authors concluded:

> This prespecified analysis of the MOMENTUM 3 trial suggests that the use of DT or BTT/BTC designations based on the current or uncertain future transplant eligibility is not necessary. Patients with medically refractory heart failure can be successfully treated under a single preimplant strategy with the goal of extending survival and improving quality of life.

Percutaneous Ventricular Assist Devices

The pVAD is another form of mechanical circulatory support. The short-term external heart assist system was introduced as an alternative to the IABP in individuals with cardiogenic shock following acute myocardial infarction (AMI). Thiele and colleagues (2005) published a randomized controlled trial comparing subjects who received the TandemHeart system (n=21) to those who received IABP (n=20). The primary outcome measure revealed that the cardiac power index rose in both groups, but was significantly higher in the TandemHeart group. The overall mortality at 30 days was similar for the two groups with a result of 43% in the TandemHeart population versus 45% in the IABP population. However, adverse events such as leg ischemia (n=7 vs. n=0), severe bleeding (n=19 vs. n=8), and fever or sepsis (n=17 vs. n=10) were higher among the TandemHeart participants. Researchers reported a median duration of device use of 3.5 days for the TandemHeart compared to 4.0 days for the IABP.

Burkhoff and colleagues (2006b) conducted a randomized controlled trial to determine if the TandemHeart system provided superior hemodynamic support compared with the IABP. Individuals presenting within 24 hours with cardiogenic shock were included into the roll-in phase (n=9) and the others randomized to treatment with TandemHeart (n=19) or IABP (n=14). Of the 42 subjects enrolled, only 62% had a diagnosis of AMI, and of these,

52% underwent percutaneous coronary intervention (PCI). Both devices had a median use of 2.5 days. In the randomized population, the study demonstrated a hemodynamic improvement of 37% in the TandemHeart group (n=7) compared to 14% in the IABP group (n=2). The TandemHeart group reported 3.1 average adverse events per participant versus the IABP group which reported 2.6 average adverse events per participant; however, there were no specific identified trends. Overall 30-day mortality was not significantly different between the two treatment groups. Authors concluded that there was no survival benefit when comparing TandemHeart with conventional therapy with IABP.

In a prospective study, Seyfarth (2008) compared the use of Impella LP 2.5 (n=12) to IABP (n=13) in participants with cardiogenic shock due to AMI. Primary improvement was measured by the change in cardiac index 30 minutes after implantation, with the Impella LP 2.5 demonstrating significant improvement. The overall 30-day mortality for both groups was reported at 46%. Researchers stated:

> A major limitation of the study is the small number of patients, which did not allow for a meaningful evaluation of potential mortality differences. Therefore, evidence from this initial study can only serve as support for future larger studies to test for a clinical benefit or mortality reduction.

Cheng and colleagues (2009) conducted a meta-analysis of randomized controlled trials (Burkhoff, 2006b; Seyfarth, 2007; Thiele, 2005) to study the benefit of pVAD on hemodynamic and survival 30 days after the procedure. Researchers concluded that individuals in the pVAD group had higher cardiac indexes, higher mean arterial pressures and lower pulmonary capillary wedge pressures compared to the IABP population. The groups had similar mortality at day 30. There were notably higher bleeding adverse events reported in the TandemHeart group compared to IABP (relative risks [RR] 2.59. 95% confidence interval [CI] 1.40-3.93). The authors concluded:

> Although use of pVAD resulted in a better hemodynamic profile compared with IABP counterpulsation, this did not translate into improved 30-day survival. Moreover, patients treated with a pVAD tended to have a higher incidence of leg ischemia and device-related bleeding.

The 2009 update of ACC/AHA guidelines for the diagnosis and management of heart failure in adults briefly address the role of mechanical circulatory assist devices, also known as pVADs:

> The use of mechanical circulatory assist devices in endstage heart failure is an area of intense investigation. Extracorporeal devices can be used for short-term circulatory support in patients who are expected to recover from a major cardiac insult (e.g., myocardial ischemia, postcardiotomy shock, or fulminant myocarditis).

While the ACC/AHA guideline does describe a potential role for short term circulatory support, the document does not provide a formal recommendation for use, or elucidate individual selection criteria or clinical situations where use of such devices have been shown to improve outcome results (Hunt, 2009).

O'Neill and colleagues (2012) reported results from the PROTECT II study, a prospective, randomized trial comparing hemodynamic support with Impella 2.5 versus IABP in individuals undergoing high-risk percutaneous coronary intervention. Enrollment was planned for 654 participants from 50 clinical centers. The study randomly assigned 452 symptomatic participants to the Impella (n=226) or IABP (n=226). The primary endpoint was the composite rate of 10 major adverse events including death, myocardial infarction, stroke or transient ischemic attack and repeat revascularization at discharge or 30 days follow-up, whichever was longer. In late 2010 the trial was discontinued prematurely due to futility, after an interim analysis revealed that the primary endpoint could not be reached. At this point, 69% of the planned enrollment for the study had been enrolled. These results reported composite adverse event rates of 35.1% in the Impella 2.5 group compared to 40.1% in the IABP group (p=0.227).

The 2015 Society of Cardiovascular Angiography and Intervention (SCAI)/ ACC/ Heart Failure Society of America (HFSA), and the Society of Thoracic Surgery (STS) provided a joint Expert Consensus Statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care. The statement addresses IABPs, left atrial-to-aorta assist devices, left ventricle-to-aorta assist devices, extracorporeal membrane oxygenation, and methods of right-sided support. The Expert Consensus document did not include specific graded recommendations, but the statement reviews the use of MCS in individuals undergoing high-risk PCI, those with cardiogenic shock, and individuals with acute decompensated heart failure. The authors concluded that

> The availability of percutaneous MCS has broadened therapeutic options for patients that require hemodynamic support. A variety of devices are now available, each with specific technical and clinical nuances. Unfortunately, definitive clinical evidence is in many cases unavailable or controversial.

Currently there is limited evidence to support if pVADs improve the net health outcome in individuals with cardiogenic shock that occurs immediately following acute myocardioal infarction (AMI), open heart surgery, or in the setting of either peripartum cardiomyopathy or myocarditis; or in high-risk PCI performed in elective or urgent setting, in hemodynamically stable individuals with severe coronary artery disease and depressed left ventricular ejection fraction. Although early study findings suggest that hemodynamic measures with the pVAD versus the IABP are comparable, clinically meaningful outcomes and subsequent reduction in mortality have not been demonstrated between the use of pVAD and IABP. The studies do not permit conclusion with respect to the use of these pVADs in individuals in cardiogenic shock due to AMI, peripartum cardiomyopathy , myocarditis, high-risk PCI or other causes, and its use often extends beyond the timeframe that is part of the FDA clearance (Cheng, 2009; O'Neill, 2009; O'Neill, 2014).

Currently cardiogenic shock remains the most deadly complication post MI, with a > 40% mortality rate for those that develop cardiogenic shock. In individuals with refractory cardiogenic shock, pVADs may be used as an alternative to ECMO or failed IABP support when the prognosis is not futile. Recently published data from observational studies (Basir, 2019; Tehrani, 2019) support the use of pVADs in cardiogenic shock protocol-based approach emphasizing "best practices" across the country and as a guide in clinical decision-making. Use of pVAD may have a clinical role in the treatment of certain individuals with refractory cardiogenic shock. The authors concluded that further studies are needed to demonstrate which individuals would benefit most from mechanical circulatory support.

Artificial Heart Systems

The published data on the SynCardia temporary Total Artificial Heart (TAH-T) (SynCardia Systems, Inc., Tucson, AZ), formerly known as CardioWest TAH-t, consists mainly of information reported by specific heart transplant centers evaluating the device under guidelines approved by the FDA, as part of an investigational device exemption (IDE). Accordingly, there is overlap among the populations in the studies. The following summarizes the results of several published studies.

Copeland and colleagues (2004a) presented a nonrandomized, prospective study in five centers with the use of historical controls to assess the safety and efficacy of the CardioWest TAH-t in transplant-eligible individuals at risk for imminent death from irreversible biventricular cardiac failure. The primary end points included the rates of

survival to heart transplantation and of survival after transplantation. A total of 81 participants received the artificial-heart device. The rate of survival to transplantation was 79%. Of the 35 control participants who met the same entry criteria but did not receive the artificial heart, 46% survived to transplantation. Overall, the 1-year survival rate among the participants who received the artificial heart was 70%, as compared with 31% among the controls. One-year and 5-year survival rates after transplantation, among individuals who had received a total artificial heart (TAH) as a bridge to transplantation, were 86% and 64%. The investigators concluded that implantation of the TAH improved the rate of survival to cardiac transplantation and survival after transplantation. Furthermore, they implied that this device prevents death in critically ill individuals who have irreversible biventricular failure and are candidates for cardiac transplantation. The study was initiated in January 1993 and concluded in September 2002.

Copeland and colleagues (2004b) presented a single center 9-year heart study. The study was conducted between January 1, 1993 and April 1, 2002 and followed 62 participants who received the CardioWest TAH-t after failing other medical therapies. All 62 participants were critically ill with biventricular heart failure. The study found that after a mean support time of 92 days, 77% of TAH participants survived to transplantation, with 88% of those surviving to discharge from the hospital after transplantation.

One published study (Copeland, 2001) retrospectively reviewed results for survival, stroke, and infection in 43 participants implanted with the CardioWest TAH-t, 23 with the Novacor® Left Ventricular Assist System (LVAS), and 26 with the Thoratec Ventricular Assist System (VAS). Respective results for CardioWest TAH-t, Novacor, and Thoratec participants included survival to transplantation, 75%, 57% and 38%; stroke, 8%, 32% and 12%; and death from infection, 2%, 13% and 4%. The authors concluded that in participants who are hemodynamically unstable or deteriorating rapidly, or have clinical right heart failure and who are large (BSA greater than1.7 m^2), the CardioWest should be used. If they are small (BSA less than or equal to 1.7 m^2), they use the Thoratec VAS. If participants are slowly deteriorating on inotropic support and have no clinical right heart failure with reasonable renal function and BSA greater than1.7 m^2, they use the Novacor LVAS. If they are similarly stable and smaller, they use the Thoratec VAS.

Arabia and colleagues (1999) reported on 24 heart transplant candidates (Group A) that met strict entry criteria and underwent placement of the CardioWest TAH-t between January 1993 and July 1996. The control group (Group B) consisted of 18 heart transplant candidates who met the TAH entry criteria but never received a TAH. The mean values (preimplantation) for Groups A and B, respectively, were age: 47 and 47 years; BSA: 2.01 and 1.93 m^2;

cardiac index: 1.5 and 1.8 L/min/m²; pulmonary vascular resistance: 2.88 and 2.47 Wood units; creatinine: 1.5 and 1.6 mg/dl; and bilirubin: 1.8 and 1.4 mg/dl. In Group A, 1 subject died on the TAH, 1 subject died after transplant, and 22 subjects reached transplant and were discharged home for a survival rate of 91.7%. In Group B, 10 subjects died while waiting for a heart transplant. Of the 8 subjects transplanted, 7 survived and were discharged home for a survival rate of 38.9%. The authors concluded that the CardioWest TAH-t provided an excellent and successful method of bridging individuals to heart transplantation with a reasonable risk.

The AbioCor implantable replacement heart system has recently received FDA approval as destination therapy for certain individuals with end stage biventricular failure. Data reviewed by the FDA on the AbioCor device included a total of 14 subjects with biventricular failure who were ineligible for cardiac transplantation, not treatable with an LVAD, receiving optimal medical management and whose expected 30-day survival was 30% or less. Data had been published previously on 7 of these 14 subjects (Dowling, 2003 and 2004) and 11 of the 14 (Frazier, 2004). All subjects were males, in part related to individual size requirements. Of the 14, 12 survived the surgical procedure, with the mean survival time being 4.5 months, and 2 subjects survived for longer than 6 months with the longest survival being 17 months. Four subjects were able to spend some time on out-of-hospital activities, however, the exact nature of these is undefined. Only 2 subjects were able to be discharged from the hospital and only 1 of these returned home. Quality of life (QOL) measures suggested improvement at "at least one point in time" in 7 subjects, but the timing of the measurements is unclear, and whether the participants truly experienced significant improvements in QOL is difficult to assess. Many adverse events occurred including 9 subjects suffering CVAs, leading to discontinuation of support in 6 of these. Most participants experienced problems with bleeding and anticoagulation, as well as infections (unrelated to the device). There were two instances of device failure.

The AbioCor heart may eventually be an attractive option as destination therapy in appropriately selected individuals, because the system is totally implantable requiring no percutaneous line attachments, and initial data regarding the technical functioning of the device appears encouraging. However, additional clinical studies are needed with larger numbers of individuals to enable further analysis of outcomes including QOL issues, survival, and adverse complications. Based on the sparse clinical data and outcomes information currently available, the device is considered investigational and not medically necessary.

The Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination (NCD 20.9, 2010) that provides indications for the use of VADs to include postcardiotomy, bridge-to-transplant, and destination therapy, subject to FDA-approved labeling and additional stipulated facility and registry participation

requirements. At the present time, CMS considers devices used as a replacement for the human heart (total artificial hearts) noncovered, due to the lack of what CMS considers authoritative evidence to substantiate safety and effectiveness.

Background/Overview

Description of Disease

Chronic heart failure is an extremely common condition estimated to affect around 3 to 5% of people over 65 years of age. Around 300,000 Americans are estimated to suffer from chronic heart failure, and the prevalence also appears to be rising. Approximately 82% of individuals with heart failure die within 6 years of diagnosis. End-stage heart failure also leads to many restrictions in lifestyle and a poor quality of life. Initial treatments for heart failure are lifestyle changes and pharmacological therapy with drugs, such as ACE inhibitors, beta blockers and diuretics. This therapy, however, often becomes inadequate, and eventually the only treatment left is a heart transplant.

Functional Description of Ventricular Assist Devices

Ventricular assist devices are pumps designed to assist, but not replace, the heart muscle. They are most commonly used to support the left ventricle, but right ventricular devices are also used. VADs have generally been used as a bridge to transplant, but in some individuals they have also been used as permanent assist devices (destination therapy). In some individuals, the implantation of an assist device has taken pressure away from the natural heart and has allowed the heart to recover, thus VADs can also provide a "bridge to recovery."

The LVAD is a pump with a tube that pulls blood from the left ventricle (pumping chamber of the heart) into a pump. The pump then sends blood into the aorta (the large blood vessel leaving the left ventricle) and from there it circulates throughout the body. This bypasses the weakened pumping chamber of the heart. Occasionally, an individual will require the simultaneous use of two VADs, one placed in the left ventricle and one in the right. The median duration for time on the device is between 20 and 120 days, but much longer times have been reported. Depending on the type of VAD used, an individual may stay in the hospital or be discharged**.** As a means of myocardial recovery support in individuals post-cardiotomy, the median duration of VAD support reported was 6 days (mean 12 days, maximum: 80 days).

The U.S. Food and Drug Administration (FDA) has approved several durable VADs for marketing which include the following:

- *The HeartMate II*® (Abbott Cardiovascular, Plymouth, MN) is a LVAD indicated for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate II is intended for use both inside and outside the hospital, or for transportation of VAD individuals via ground ambulance, fixed-wing aircraft, or helicopter (US FDA HeartMate II PMA Approval, 2008). In 2010, the FDA extended the PMA approval for coverage of the HeartMate II to include destination therapy. The device is indicated for use in people with severe heart failure, 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 who are not candidates for cardiac transplantation.

- *The HeartMate 3 Left Ventricular Assist System* is an LVAD that received premarket approval August 23, 2017 for short-term hemodynamic support (that is bridge to transplant or bridge to myocardial recovery) in individuals with BSA ≥ 1.2 m^2 who have advanced refractory left ventricular heart failure. On October 18, 2018 the FDA expanded the PMA approval for coverage of the HeartMate 3 LVAS as long-term mechanical support (that is, destination therapy) for individuals living with advanced refractory left ventricular heart failure. In December 2020 the FDA approved updating labeling for the HeartMate 3 LVAS, indicated for providing short- and long-term mechanical circulatory support in *pediatric* population with advanced refractory left ventricular heart failure and an appropriate body surface area (BSA ≥ *1.0 m^2*). Abbott Cardiovascular has agreed to work with Advanced Cardiac Therapies Improving Outcomes Network (ACTION) in the PMA Post-Approval Study HeartMate 3 Real-World Pediatric Use Surveillance study. ACTION is a consortium of 50+ U.S. Pediatric hospitals that pooled together data of HeartMate 3 LVAS outcomes in the pediatric population. The surveillance is to continue to monitor use of the HeartMate 3 LVAS performance in the pediatric population within the first 2 years after the PMA approval, that are entered into the ACTION registry. The surveillance will monitor participant outcomes and adverse events at 3, 6, 12, and 24 months. The FDA approval was based on outcomes of the MOMENTUM trial.

- *HeartWare HVAD System* is a LVAD approved for use as a bridge to cardiac transplantation in transplant candidates at risk of death from refractory end-stage left ventricular heart failure. The HeartWare VAS system includes a pump small enough to be implanted within the heart's pericardial space, allowing for

implantation in smaller adults or individuals unable to have an implant in the abdomen. The system includes an implantable pump with an external driver and power source that is designed for use in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter. On September 27, 2017 the FDA expanded approval for hemodynamic support in individuals with advanced, refractory left ventricular heart failure, for destination therapy in those who subsequent transplantation is not planned. On July 19, 2018 Medtronic received FDA approval to now include a less-invasive implant approach for the HeartWare HVAD System, the new approval allows for implantation via thoracotomy, a small incision between the ribs on the left side of the chest versus a sternotomy.

- *CentriMag® RVAS* (Thoratec Corporation, Pleasanton, CA) received Humanitarian Device Exemption in June 2008 intended to provide temporary circulatory support for up to 14 days for individuals in cardiogenic shock with acute right ventricular failure. In June 2012 the FDA expanded the Humanitarian Device Exemption for use of CentriMag RVAS as a right ventricular assist device for periods of support up to 30 days for individuals in cardiogenic shock due to acute right ventricular failure.

- *The HeartAssist 5 Pediatric VAD*, previously known as the DeBakey VAD® Child Left Ventricular Assist System received Humanitarian Device Exemption in February 2004 for *children between 5 and 16 years of age* who have end-stage left ventricular failure requiring temporary mechanical blood circulation until a heart transplant can be performed. The device is intended for both home and hospital use.

- *The Berlin Heart's EXCOR* (Berlin Heart, Inc. Woodlands, TX) is a *pediatric* VAD able to support children with severe end stage heart failure. In December 2011 the device received Humanitarian Device Exemption from the U.S Food and Drug Administration for *children between 0 and 16 years of age* who have end-stage left ventricular failure requiring temporary mechanical blood circulation until a heart transplant can be performed. The device is intended for hospital use.

Mechanical assist devices are increasingly evolving towards smaller devices that are associated with less morbidity and employ transcutaneous energy sources that avoid the almost universal risk of infection. As newer generation devices become available, there is anticipation that the morbidity associated with these devices will be lower (Mehra, 2004).

Functional description of Percutaneous Ventricular Assist Devices (Left and Right)

There are also other devices which support left ventricular function that are not classified as LVADs. For instance, the ABIOMED Impella Ventricular Support Systems (Impella Recover LP 2.5 Percutaneous Cardiac Support System, Impella CP Heart Pump and Impella Recover LP 5.0 Percutaneous Cardiac Support System; ABIOMED, Inc., Danvers, MA) can be inserted via standard catheter based procedure through the femoral artery, into the ascending aorta, across the valve and into the left ventricle. The Impella devices were cleared for marketing by the FDA through the 510(k) process to provide circulatory support using an extracorporeal bypass unit for up to 6 hours. They are intended to be used to provide circulatory support (for periods up to 6 hours) during elective or urgent high risk PCI procedures not requiring cardiopulmonary bypass. The Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure. In April 2016, the FDA expanded approval for use of Impella devices in the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction (AMI) or open heart surgery. In February 2018, the FDA extended the PMA approval for coverage of the Impella heart pumps for treatment of ongoing cardiogenic shock that occurs in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (includes volume loading and use of pressors and inotropes, with or without IABP). The intent of the Impella Support Systems therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. (Product Information, 2018). The FDA based the recent PMA expansion on safety and effectiveness data from the Impella Registry, an ongoing, multi-center, retrospective, observational registry.

On September 25, 2019 the FDA granted ABIOMED premarket approval for the Impella 5.5™ with SmartAssist®, a temporary ventricular support device intended for short term (14 days) use and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or heart surgery in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The FDA supplemental approval of the Impella 5.5 with Smart Assist stems from FDA PMA approvals indicating Impella devices as safe and effective for the treatment of cardiogenic shock. The approvals were based on data from the FDA study RECOVER I, and the U.S. Impella registry, and the Impella literature.

The TandemHeart system (Cardiac Assist, Inc., Pittsburg, PA) is intended for transseptal catheterization of the left atrium to femoral vein for the purpose of providing means for temporary left ventricular bypass which returns blood to the individuals via the femoral artery or other appropriate site. The device was cleared for marketing by the FDA through the 510(k) process with intended use for extracorporeal circulatory support using an extracorporeal bypass circuit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to 6 hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to 6 hours) for procedures not requiring complete cardiopulmonary bypass (for example, valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplantation, etc.). The Protek Duo kit is used when internal jugular venous access is more favorable; the dual lumen cannula is inserted percutaneously. The lumens are connected with the TandemHeart system.

The HeartMate PHP (Thoratec CORP, Pleasanton, CA) is a temporary (< 6 hours) percutaneous heart pump being studied for use in the SHIELD II (Coronary Interventions in High-Risk Patients Using a Novel Percutaneous Left Ventricular Support Device) U.S. IDE Clinical study. The prospective, randomized multicenter, open-label study will compare the HeartMate PHP to the Impella 2.5 in individuals undergoing high-risk PCI performed in elective or urgent, hemodynamically stable individuals with severe coronary artery disease and decreased left ventricular ejection fraction.

On September 20, 2017 Abiomed Inc. (Danvers, MA) received PMA approval for the Impella RP System, a percutaneous administered temporary right ventricular support used for up to 14 days in individuals with a body surface area greater than or equal to 1.5 m^2, who develop acute right heart failure or decompensation following left ventricular device implantation, myocardial infarction, heart transplant, or open-heart surgery. The RECOVER RIGHT trial (NCT1777607) a prospective, open label, single arm, non-randomized, multicenter study that included 2 cohorts; cohort A enrolled 18 participants who developed right ventricular failure (RVF) after LVAD implantation. Cohort B enrolled 12 participants who developed RVF 48 hours after undergoing cardiac surgery or myocardial infarction (Anderson, 2015). The Anderson and colleagues concluded that preliminary findings for the Impella RP support probable benefit in gravely ill population and suggest that the device may represent as a strategy as a bridge therapy to recovery or to a definitive therapy. The study does not permit conclusion with respect to the use of the Impella RP System in individuals with acute right heart failure or decompensation following LVAD implantation, myocardial infarction, heart transplant, or open-heart surgery.

Functional Description of the Total Artificial Heart Systems

Since the 1950's, when the heart-lung bypass machine was developed, many advances have been made in the surgical treatment of cardiovascular disease. Many surgical procedures considered impossible just a few decades ago are standards of care today. An example is heart transplantation. However, total artificial heart (TAH) technology has not evolved at the same pace. Though the first human heart transplantation and the first TAH implantation occurred within 2 years of each other, TAH implantation is still neither routine nor widely accepted.

The SynCardia TAH-t is a pneumatic, biventricular, implantable bridge-to-transplant system for full cardiac replacement, taking the place of the failing heart in individuals at imminent risk of death. The SynCardia TAH-t is attached to the upper chambers of the individual's heart after the lower chambers - the ventricles that pump blood through the body - have been removed. In March 2004, an FDA Advisory Panel voted to recommend commercial approval for the SynCardia TAH-t, provided that use of the device is limited to cardiac transplantation centers and further required that the sponsors agree to a 1-year post-market study. On October 18, 2004, the FDA approved the SynCardia TAH-t, for use as a bridge to transplant in transplant-eligible candidates at risk of imminent death from biventricular failure, subject to the FDA requirement that the manufacturer conduct a post-approval study to monitor the device's performance in commercial use.

The AbioCor Implantable Replacement Heart System (ABIOMED, Inc., Danvers, MA) is the first fully implantable prosthetic system, intended for permanent use as destination therapy for individuals with end-stage irreversible, biventricular heart failure that has not responded to optimal medical management. Candidates for this device are ineligible for heart transplant. On September 5, 2006 the FDA approved the AbioCor device under the Humanitarian Use Device (HUD) provisions of the Food, Drug and Cosmetic Act. The Center for Devices and Radiological Health (CDRH) of the FDA approved the AbioCor Implantable Replacement Heart System (ABIOMED, Inc. Danvers, Mass) for use in severe biventricular end-stage heart disease individuals who are not cardiac transplant candidates and who:

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

The FDA Advisory Panel previously rejected the approval of this device in June, 2005 based on the poor outcomes in the 14 gravely ill individuals that had received the AbioCor device (50% died from stroke; there were many cases of severe bleeding; and only 1 individual survived 17 months post-device implantation).

The 2006 HUD approval is subject to FDA requirements that a post-approval study be conducted of the first 25 individuals implanted with the AbioCor who will be followed until death while on the device or other outcome. In addition, the CDRH of the FDA may require expert panel review of study data after the first 10 individuals are implanted for further evaluation and recommendations. Currently, the literature regarding the safety and efficacy from the clinical trials has not been published. Therefore, under the HUD exemption, use of the AbioCor is limited to approved clinical trials.

The Freedom™ driver system, (SynCardia Systems, Inc., Tucson, AZ), used in combination with SynCardia TAH-t, as a bridge to transplant in cardiac transplant candidates who are clinically stable, was granted PMA approval by the FDA in July 2014. The Freedom driver is a suitable pneumatic driver for stable total artificial heart candidates who meet criteria and who may have the option to be discharged from the hospital to wait for their matching donor heart in the outpatient setting.

Definitions

Cardiogenic shock: A state of inadequate tissue perfusion where the heart is suddenly weakened and unable to pump enough blood to meet the body's needs.

Cardiopulmonary bypass: A machine that takes blood from the body, passes it through a machine that pumps oxygen into the blood and returns it to the body, bypassing the individual's own heart and lungs; this machine is commonly used during open-heart surgery.

End stage heart failure: In people with heart failure, the body does not receive an adequate supply of oxygen; as a result, they can feel weak, fatigued or short of breath; everyday activities such as walking, climbing stairs, carrying groceries and yard work can become quite difficult; in end stage heart failure, the heart is so weakened the individual will die without a heart transplant.

Guideline-directed medical therapy (GDMT): This term was adopted by the writing groups for the major specialty medical societies (such as found in Tracy, 2012 and Yancy, 2013) in 2012; the term replaces and is synonymous with "optimal medical therapy."

Heart transplant: Removal of an individual's heart and replacing it with a donor heart.

Humanitarian Device Exemption (HDE): Similar to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose and does not pose an unreasonable or significant risk of illness or injury. The use of the device is limited to 4000 or less individuals per year.

New York Heart Association (NYHA) Classification:

- Class III: Individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea (difficulty breathing) or anginal (chest) pain.
- Class IV: Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal (chest) syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Pre-Market Approval (PMA): The most stringent type of device marketing application required by the FDA. A PMA is an application submitted to the FDA to request clearance to market or to continue marketing of a Class III medical device. Class III medical devices are those devices that present significant risk to the individual and/or require significant scientific review of the safety and effectiveness of the medical device prior to commercial introduction. Frequently the FDA requires follow-up studies for these devices.

Post cardiotomy: The period of time after heart surgery.

Ventricle: One of a pair of muscular chambers of the heart that pump blood into the body.

Coding

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

~~Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.~~

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Ventricular Assist Devices and Artificial Heart Systems
When services may be Medically Necessary when criteria are met:

CPT

	Ventricular Assist Devices
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
	Artificial heart
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

ICD-10 Procedure

	Ventricular Assist Devices
02HA0QZ-02HA4QZ	Insertion of implantable heart assist system into heart [by approach; includes codes 02HA0QZ, 02HA3QZ, 02HA4QZ]
02HA0RJ-02HA4RJ	Insertion of short-term external heart assist system into heart, intraoperative [by open or percutaneous endoscopic approach; includes codes 02HA0RJ, 02HA4RJ]
02HA0RS-02HA4RS	Insertion of short-term external heart assist system into heart, biventricular [by open or percutaneous endoscopic approach; includes codes 02HA0RS, 02HA4RS]

02HA0RZ-02HA4RZ	Insertion of short-term external heart assist system into heart [by open or percutaneous endoscopic approach; includes codes 02HA0RZ, 02HA4RZ]
02WA0QZ-02WA4QZ	Revision of implantable heart assist system in heart [by approach; includes codes 02WA0QZ, 02WA3QZ, 02WA4QZ]
5A02116	Assistance with cardiac output using other pump, intermittent
5A02216	Assistance with cardiac output using other pump, continuous
	Artificial heart
02RK0JZ-02RK4JZ	Replacement of right ventricle with synthetic substitute [by approach; includes codes 02RK0JZ, 02RK4JZ]
02RL0JZ-02RL4JZ	Replacement of left ventricle with synthetic substitute [by approach; includes codes 02RL0JZ, 02RL4JZ]
02UA0JZ-02UA4JZ	Supplement heart with synthetic substitute [by approach; includes codes 02UA0JZ, 02UA3JZ, 02UA4JZ]
02WA0JZ	Revision of synthetic substitute in heart, open approach

ICD-10 Diagnosis

All diagnoses

When Services are Not Medically Necessary:
For the procedure codes listed above, when criteria are not met, or for indications listed in the Position Statement section as not medically necessary.

When Services are Investigational and Not Medically Necessary:
For the procedure codes listed above, for all other indications, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

Percutaneous Ventricular Assist Devices (pVADs)
When services may be Medically Necessary when criteria are met:

CPT

33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only

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33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

ICD-10 Procedure

02HA3RJ	Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach
02HA3RS	Insertion of short-term external heart assist system into heart, biventricular, percutaneous approach
02HA3RZ	Insertion of short-term external heart assist system into heart, percutaneous approach
02HL3DZ	Insertion of intraluminal device into left ventricle, percutaneous approach [when specified as pVAD device]
5A0211D	Assistance with cardiac output using impeller pump, intermittent
5A0221D	Assistance with cardiac output using impeller pump, continuous

ICD-10 Diagnosis

R57.0	Cardiogenic shock
T81.11XA-T81.11XS	Postprocedural cardiogenic shock

When services are Investigational and Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met, or for all other indications.

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~~Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.~~

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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	02/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN LVAD destination therapy criteria in adults. Revised MN statement for pediatric LVAD using HeartMate 3 to include criteria for destination therapy. Updated Rationale, Background, References and Websites sections.
Revised	11/05/2020	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. Removed examples of optimal medical management from LVAD destination therapy MN statement and moved to Rationale section. Updated Rationale, Background, References and Websites sections. Updated Coding section with 01/01/2021 CPT descriptor changes and added 33995 effective 01/01/2021.
Revised	11/07/2019	MPTAC review. Added MN statement for use of FDA approved pVAD used in accordance with FDA approval for treatment of cardiogenic shock when criteria met. Added "Note" referring to background section of the document for list of FDA approved pVADs. Revised I/NMN statement for pVAD, removing list of devices. Updated Description, Rationale, Background, References, Websites and Index sections. Updated Coding section, including removal of CPT 33992.
Reviewed	08/22/2019	MPTAC review. Updated Description, Rationale, Background, References and Websites sections.
Reviewed	11/08/2018	MPTAC review. Updated Rationale, Background, References and Websites sections.
Revised	07/26/2018	MPTAC review. Added Impella CP Heart Pump to list of examples of pVADs considered I/NMN. Updated Description, Background, Index, References and Websites sections.

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Reviewed	03/22/2018	MPTAC review. Updated Rationale, Background, References and Websites sections.
Revised	01/25/2018	MPTAC review. Clarified MN statement for VADs "appropriate for pediatrics" when used in accordance with FDA approval and added reference to HeartMate 3 LVAS (FDA approved without a specific age requirement) when BSA criteria met. Updated Background, References, and Websites sections.
Revised	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Clarified MN statement "FDA VADs used in accordance with FDA approval, when criteria met. Added "Note" referring to background section of the document for list of FDA approved VADs. Added Impella RP to list of examples of pVADs considered I/NMN. Updated Rationale, Background, Index, References and Websites sections. Updated Coding section with 01/01/2018 CPT changes; removed 0051T, 0052T, 0053T deleted 12/31/2017, added 33927, 33928, 33929 effective 01/01/2018.
Reviewed	08/03/2017	MPTAC review. Updated References and Websites sections. Updated Coding section to include 10/01/2017 ICD-10-PCS changes.
Reviewed	11/03/2016	MPTAC review. Updated formatting in position statement section. Document re-categorized to SURG.00145. Updated Description, Rationale, References and Index sections.
Revised	11/05/2015	MPTAC review. Clarified pVAD investigational and not medically statement to include HeartMate PHP in example of devices used. Revised medically necessary, not medically necessary and investigational and not medically necessary statements for CardioWest Total Artificial Heart (TAH-t) to reflect new name SynCardia temporary Total Artificial Heart (TAH-t). Updated Description, Rationale, Background, Definitions, Index, References and Websites sections. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. Defined abbreviations in medically necessary and investigational and not medically necessary statements Reformatted artificial heart systems medically necessary criteria. Updated Description, Rationale, Background, References and Websites sections.

Revised	08/14/2014	MPTAC review. Clarified medically necessary statement to define U.S. Food and Drug Administration (FDA). Updated Description, Rationale, References and Websites.
Reviewed	08/08/2013	MPTAC review. Updated Rationale and Reference section.
Reviewed	02/14/2013	MPTAC review. Rationale and Websites Updated.
	01/01/2013	Updated Coding section with 01/01/2013 CPT changes; removed 0048T, 0050T deleted 12/31/2012.
Revised	02/16/2012	MPTAC review. Formatting change.
Revised	01/18/2012	MPTAC review. Revised pediatric ventricular assist device medically necessary statement addressing adjusted age requirement and investigational and medically necessary contraindication. Updated Background.
Revised	08/18/2011	MPTAC review. Title change. Added investigational and not medically necessary position statement for percutaneous ventricular assist devices. Updated Rationale and Background. Added definition. Updated Coding, Index, References and Websites.
Reviewed	05/19/2011	MPTAC review. Updated Background, Definitions, Index, References and Websites.
Revised	05/13/2010	MPTAC review. Additional criteria for coverage added to the ventricular assist devices (VAD) bridge to heart transplant medically necessary position statement. Clarified medically necessary position statement. Background, coding and references updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes.
Reviewed	08/27/2009	MPTAC review. Rationale and references updated.
	01/01/2009	Updated Coding section with 01/01/2009 CPT changes; removed CPT 0049T deleted 12/31/2008.
Reviewed	08/28/2008	MPTAC review. References updated. Updated coding with 10/01/2008 ICD-9 changes.
Reviewed	11/29/2007	MPTAC review. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." No change to criteria. References were updated.

Revised	12/07/2006	MPTAC review. A statement was added to address the AbioCor Implantable Replacement Heart System as investigational/not medically necessary. References and coding sections were also updated.
Reviewed	03/23/2006	MPTAC review. No changes to criteria. References and coding were updated.
	11/17/2005	Added reference for Centers for Medicare & Medicaid Services (CMS) - National Coverage Determination (NCD).
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	07/27/2004	TRANS.00014	Ventricular Assist Devices
WellPoint Health Networks, Inc.	12/02/2004	3.04.27	Total Artificial Heart as a Bridge to Transplantation
	12/02/2004	3.04.23	Ventricular Assist Devices