BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Total Artificial Hearts and Related Devices

Policy #: 033
Latest Review Date: September 2022
Category: Surgery

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).*

POLICY:

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

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.

Blue Advantage will treat **implantable aortic counterpulsation ventricular assist devices** (e.g., the NuPulseCV iVAS and the Symphony Heart Assist System) as a **non-covered benefit** and **investigational** for all indications.

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.

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:

According to a 2022 report from the American Heart Association and based on data collected from 2015 to 2018, roughly 6 million Americans ages 20 years or older had heart failure during that time frame. Prevalence of heart failure is projected to affect more than 8 million people 18 years of age and older by the year 2030. Between 2015 and 2018, the prevalence of heart failure was highest in non-Hispanic Black males. Based on data from the Multi-Ethnic Study of Atherosclerosis (MESA), in those without baseline cardiovascular disease, Black individuals had the highest risk of developing heart failure (4.6 per 1000 person-years), followed by Hispanic (3.5 per 1000 person-years), White (2.4 per 1000 person-years), and Chinese individuals (1.0 per 1000 person-years). Similar findings were demonstrated in the Atherosclerosis Risk in Communities (ARIC) Community Surveillance data, in which Black men and women had the highest burden of new-onset heart failure cases and the highest-age adjusted 30-day case fatality rate in comparison to White men and women. Higher risk reflected differential prevalence of hypertension, diabetes, and low socio-economic status.

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 that 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.

KEY POINTS:

The most recent literature search was performed for the period through June 22, 2022.

Summary of Evidence

Total Artificial Heart

For individuals who have end-stage heart failure who receive a TAH as a bridge to transplant, the evidence includes case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

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 mechanical circulatory support (MCS), including both durable and nondurable MCS devices. The guidelines categorized pVADs and extracorporeal ventricular assist devices (VADs) as nondurable MCS devices. Since the 2017 update, these guidelines have been updated regularly, with the most recent update occurring in 2022. Table 2 provides recommendations on MCS devices from the most recently updated guideline iteration.

Table 2. AHA/ACC/HFSA Guidelines on Mechanical Circulatory Support

Recommendation	COE[a]	LOE[b]
"In select patients with advanced HFrEF with NYHA class IV symptoms who are deemed to be dependent on continuous intravenous inotropes or temporary MCS, durable LVAD implantation is effective to improve functional status, QOL, and survival."	I	A
"In select patients with advanced HFrEF who have NYHA class IV symptoms despite GDMT, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality."	IIA	B-R
"In patients with advanced HFrEF and hemodynamic compromise and shock, temporary MCS, including percutaneous and extracorporeal ventricular assist devices, are reasonable as a 'bridge to recovery' or 'bridge to decision"	IIA	B-NR

American Heart Association

In 2012, the AHA published recommendations for the use of MCS. These guidelines defined nondurable MCS as IABPs, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 3 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 3. 2012 Guidelines on Mechanical Circulatory Support

Recommendation	COE	LOE
"MCS for BTT indication should be considered for transplant-eligible patients with end-stage HF who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation."	I	B

"Implantation of MCS in patients before the development of advanced HF … is associated with better outcomes. Therefore, early referral of HF patients is reasonable."	IIA	B
"MCS with a durable, implantable device for permanent therapy or DT is beneficial for patients with advanced HF, high 1-year mortality resulting from HF, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation."	I	B
"Elective rather than urgent implantation of DT can be beneficial when performed after optimization of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies."	IIA	C
"Urgent nondurable MCS is reasonable in hemodynamically compromised HF patients with end-organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile." "These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF."	IIA I	C C
"Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS."	IIA	B

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable

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:

Total Artificial Heart

In 2004, FDA approved the temporary CardioWest™ Total Artificial Heart (SynCardia Systems) 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, FDA approved the AbioCor® Implantable Replacement Heart System (Abiomed) 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.**

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

33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)

As of 1/1/22, aortic counterpulsation ventricular assist devices should be reported using the unlisted code below.

33999	Unlisted procedure, cardiac surgery

HCPCS Codes:

L8698	Miscellaneous component, supply or accessory for use with total artificial heart system

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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
Medical Policy Group, August 2021
Medical Policy Group, December 2021: 2022 Annual Coding Update. Moved CPT codes from Current coding section. Updated Previous Coding section to include codes 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 0457T, 0458T, 0459T, 0460T, 0461T, and 0462T. Added unlisted CPT Code 33999 to Current Coding section. CPT Code 33999 will be used to report permanently implantable aortic counterpulsation ventricular assist devices after 1/1/2022.
Medical Policy Group, September 2022
