BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Total Artificial Hearts and Related Devices

Policy #: 033
Latest Review Date: September 2024
Category: Transplant

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:

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.

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 2024 report from the American Heart Association and based on data collected from 2017 to 2020, roughly 6.7 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 individuals 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 had a reported survival rates at of nearly 92% for transplants performed in 2022. 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)

The total artificial heart is 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 individuals, but is currently experimental.

KEY POINTS:

The most recent literature search was performed for the period through June 24, 2024.

Summary of Evidence

Total Artificial Heart

For individuals who have end-stage heart failure who receive a total artificial heart (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 individuals 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.

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

The total artificial heart (TAH) is a biventricular device that completely replaces the function of the diseased heart. An internal battery needs frequent recharging from an external power source. Several systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

Currently, the Syncardia Temporary Total Artificial Heart (Syncardia Systems) is the only Total Artificial Heart available in the US (Table 6). The AbioCor Total Artificial Heart was FDA approved under the Humanitarian Device Exemption program in 2006, but is no longer being marketed or in development.

Table 6. Available Total Artificial Heart

Device	Manufacturer	Approval	FDA	PMA	Indication

		Date	Clearance	No.	
SynCardia Temporary Total Artificial Heart (Formerly CardioWest Total Artificial Heart and Jarvik Total Artificial Heart)	SynCardia Systems	2004	510(k)	P030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

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

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
Medical Policy Group, September 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, September 2024
UM Committee, September 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

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.