Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 10/1/2024
Policy Number: ccp.1250	**Effective Date:** 10/2016 **Revision Date:** September 1, 2024
Policy Name: Total artificial heart	

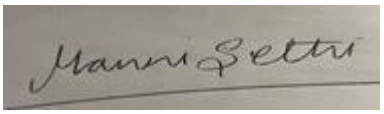
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Total artificial heart

Clinical Policy ID: CCP.1250

Recent review date: 9/2024

Next review date: 1/2026

Policy contains: Heart failure; mechanical circulatory support; total artificial heart.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

The SynCardia Temporary Cardio West Total Artificial Heart (TAH-t; SynCardia Systems, LLC, Tucson, Arizona) is clinically proven and, therefore, may be medically necessary as a bridge to transplantation when implantation is performed at a Medicare-approved heart transplantation facility or at a facility with a United Network for Organ Sharing-approved heart transplantation program for members who meet all of the following criteria (Feldman 2013; Peura, 2012; Ponikowski, 2016):

- Candidate for heart transplantation or is undergoing evaluation to determine candidacy for heart transplantation.
- Biventricular failure.
- Not expected to survive until a donor heart can be obtained.
- No other surgical or medical treatment options.
- Ineligible for univentricular or biventricular support devices.
- Receiving maximal medical therapy including intravenous inotropic support.

The Abiocor® Implantable Replacement Heart (Abiomed, Inc., Danvers, Massachusetts) is clinically proven and, therefore, medically necessary as destination therapy under a Humanitarian Device Exemption for members who meet all of the following criteria (U.S. Food and Drug Administration, 2006):

- Not a candidate for heart transplantation.
- Not treatable by left ventricular assist device destination therapy.
- Not weanable from biventricular support if on such support.
- Severe biventricular end stage heart disease.

- Less than 75 years of age.
- Require multiple inotropic support.

Limitations

All other uses of the total artificial heart are not medically necessary.

Absolute contraindications to the total artificial heart include conditions that would generally exclude patients for heart transplantation, including, but not limited to (Peura, 2012; Yancy, 2013):

- Chronic irreversible hepatic or respiratory failure.
- Irreversible kidney failure unless bridge to heart–kidney transplantation is considered.
- Active systemic infection or prolonged intubation.
- Coagulation disorders.
- Irreversible kidney failure unless bridge to heart–kidney transplantation is considered.
- Insufficient space in the thorax and/or abdominal cavity for the device.
- Structural heart disease that prohibits or may interfere with a successful implantation (e.g., uncorrected valvular disease).
- Underlying coagulopathy, either an international normalized ratio < 2.5 or a platelet count < 50,000. A contraindication to anticoagulation is a contraindication to mechanical circulatory support in most situations.

Relative contraindications to the total artificial heart include, but are not limited to (Peura, 2012; Ponikowski, 2016):

- Age > 75 years for destination therapy.
- Obesity > 40 kg/m^2 or malnutrition.
- Musculoskeletal disease that impairs rehabilitation.
- Untreated malignancy.
- Severe peripheral vascular disease.
- Active substance abuse.
- Impaired cognitive function.
- Unmanaged psychiatric disorder.
- Inadequate psychosocial support.

Alternative covered services:

- Cardiac rehabilitation.
- Cardiac resynchronization (implantable cardioverter-defibrillator; cardiac resynchronization therapy).
- Continuous intravenous inotropic infusion.
- Corrective surgery (e.g., coronary artery bypass or valve replacement).
- Extracorporeal membrane oxygenation.
- Heart transplantation.
- Intra-aortic balloon pump.
- Percutaneous coronary intervention.
- Pharmacologic therapy, including but not limited to: angiotensin-converting enzyme inhibitors; angiotensin II receptor blockers (or inhibitors); angiotensin-receptor neprilysin inhibitors; I_f channel blocker (or inhibitor); beta blockers; aldosterone antagonists; hydralazine and isosorbide dinitrate (specifically benefits African Americans with heart failure); diuretics; digoxin; statins; and anticoagulants.

Background

Heart failure is a complex clinical syndrome resulting from any structural or functional impairment of ventricular filling or ejection of blood that fails to meet the body's needs (Yancy, 2013). Disorders of the pericardium, myocardium, endocardium, heart valves, great vessels, or certain metabolic abnormalities can cause heart failure and lead to episodes of arrhythmia, increasing pump failure, and premature death. Dyspnea and fatigue are the principal symptoms of heart failure; infants may also present with poor feeding, poor growth, excessive sweating, or even low blood pressure.

The class and type of heart failure are important considerations for managing patients with heart failure (American Heart Association, 2023). Most patients with heart failure have symptoms due to left ventricular impairment. Several validated classification systems are available to grade the severity of heart failure, including: the four-stage New York Heart Association functional classification; the American College of Cardiology/American Heart Association staging system (Hunt, 2009); the European Society of Cardiology (Ponikowski, 2016) system; and the Ross Classification System for infants and younger children (Rosenthal, 2004). The Interagency Registry for Mechanically Assisted Circulatory Support (2020), which acquires data on patients supported with U.S. Food and Drug Administration-approved mechanical circulatory support devices, further stratifies patients with advanced heart failure into seven clinical profiles by their signs and symptoms (See Appendix).

A subset of patients with chronic heart failure will continue to progress and develop persistently severe symptoms despite maximum guideline-directed medical therapy. Patients with advanced heart failure typically have symptoms at rest or with minimal exertion and cannot perform many activities of daily living. They are usually classified as American College of Cardiology/American Heart Association stage D or New York Heart Association Class IV and have clinically significant circulatory compromise (see Appendix).

Advanced heart failure is a debilitating condition for which heart transplantation offers the best treatment option. However, the supply of donor hearts is diminishing, and demand greatly exceeds supply. The shortage of donor hearts has encouraged the development of artificial mechanical devices that can assist or replace the function of the failing heart. A ventricular assist device is an electromechanical pump attached to the native heart and vessels to augment cardiac output. It is designed to partially or completely assist the ventricles of the native heart.

A total artificial heart is attached to the pulmonary artery and aorta; it is designed to completely replace cardiac function and generally requires the removal of the patient's heart. The U.S. Food and Drug Administration (2006, 2023) has approved two total artificial hearts for marketing in the United States: the SynCardia Temporary Cardio West total artificial heart and the Abiocor Implantable Replacement Heart.

The Abiocor Implantable Replacement Heart was approved as a Humanitarian Use Device within the Humanitarian Device Exemption regulatory pathway as destination therapy designated for patients with rare diseases or conditions that affect or are manifested in not more than 8,000 individuals in the United States per year. This pathway exempts the Abiocor from the effectiveness requirements of other regulatory pathways and subjects the device to certain profit and use restrictions.

The SynCardia 70cc model with a Circulatory Support System console (external pneumatic driver) received government approval as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The device was indicated for patients with body surface areas of at least 1.7 m^2 for inpatient use only. In 2012, the U.S. Food and Drug Administration approved a smaller Companion 2 (C2) Driver system for hospital use conditioned on a post-approval surveillance study to assess post-market performance. The final analysis indicated a higher mortality rate and higher stroke rate for patients initially supported with the SynCardia C2 Driver System compared to patients supported with the initial generation driver (Hicks, 2018). The

Administration recommended that practitioners carefully consider these results when making treatment decisions, discuss the risks and benefits of the C2 Driver System with patients, and voluntarily report any adverse events or suspected adverse events.

In 2014, the SynCardia Freedom® Portable Driver was approved for use at home. Both drivers facilitate recovery by allowing ambulation, aggressive physiotherapy, and eventual hospital discharge (Noly, 2020). In March of 2020, the U.S. Food and Drug Administration approved a smaller SynCardia model called the 50cc temporary Total Artificial Heart suitable for smaller statured adults and pediatric patients.

As of mid-2022, the SynCardia total artificial heart has been implanted in over 2,000 patients worldwide (Henn, 2022). The number of total artificial heart procedures is increasing. In the U.S., procedures rose from 9 to 63 from 2004-2006 to 2009-2011, according to a 20% national sample (Pasha, 2022).

Findings

A guideline from the American Association for Thoracic Surgery and International Society for Heart and Lung Transplant states that total artificial heart as initial management can benefit patients with advanced right ventricular failure (Kirklin, 2020).

A guideline from the European Society of Cardiology supports mechanical circulatory support, including total artificial heart, as a bridge to transplant for patient with advanced heart failure alive at high risk of death before transplant prior to organ donation (McDonagh, 2021).

A guideline from the United Kingdom states that total artificial heart implant for end-stage biventricular should only be used with special arrangements, consent, or research, due to limited evidence of effectiveness (National Institute for Health and Care Excellence, 2017).

Few randomized comparative studies are available to guide patient or device selection for the patient requiring mechanical circulatory support beyond criteria established for U.S. Food and Drug Administration approval. In adult populations, some generalizations from consensus-based guidelines can be made:

- As bridge to transplantation, total artificial hearts are available for patients with biventricular heart failure who meet criteria for heart transplantation and are at risk of imminent death. The effectiveness of temporary total artificial heart has been established only in patients with idiopathic and ischemic cardiomyopathies in a hospital setting (Ponikowski, 2016).
- The safety and efficacy of the total artificial heart as destination therapy or when used with a portable driver outside the hospital setting have not been established (Peura, 2012). Patient selection is based on enrollment criteria in pivotal randomized controlled trials used to support U.S. Food and Drug Administration approval. Studies have not validated other preoperative variables to further refine patient selection and thereby improve patient outcomes.

In 2018, the policy ID was changed from CP# 04.02.07 to CCP.1250.

In 2019, we removed ventricular assist devices from the policy. The coverage policy will focus solely on the total artificial heart, for which we identified no new information to add.

In 2020, we removed references and text that addressed only ventricular assist devices. We added patient outcome data from an Interagency Registry for Mechanically Assisted Circulatory Support study inclusive of 450 patients who received a total artificial heart between June 2006 and April 2017 (Arabía, 2018). Most patients were Interagency Registry for Mechanically Assisted Circulatory Support Profile 1 (43%) or 2 (37%) at implantation representing severe, rapidly declining dilated cardiomyopathy and ischemic cardiomyopathy. Two

hundred sixty-six patients underwent transplantation, and 162 died. Overall 3-, 6-, and 12-month actuarial survival rates were 73%, 62%, and 53%, respectively. Risk factors for death included older age (P = .001), need for pre-implantation dialysis (P = .006), higher creatinine (P = .008) and lower albumin (P < .001) levels, and implantation at a low-volume center (defined as ≤ 10 total artificial heart procedures during study period; P < .001). Experienced centers have better outcomes, likely related to patient selection, timing of implantation, patient care, and device management.

We included a systematic review and meta-analysis of 12 studies comparing the SynCardia total artificial heart to the HeartWare™ HVAD™ system (Medtronic, Minneapolis, Minnesota) used off-label as biventricular support for management of biventricular heart failure (Maynes, 2020). The results from 512 recipients in the SynCardia group and 38 recipients in the HeartWare group were pooled for meta-analysis. The groups were statistically comparable at baseline. There were no statistically significant differences between the groups with respect to post-operative bleeding (P = .22) and overall mortality at 120 days (P = .44). SynCardia recipients had a shorter duration of support (mean = 71 days, 95% confidence interval, 15 days to 127 days versus 167 days, 95% confidence interval 116 days to 217 days, P = .01). However, HeartWare recipients were more likely to be discharged home on support (73% versus 6% P < .01).

We added information on the Abiocor total artificial heart to the coverage section, as it is approved for use as destination therapy under a Humanitarian Device Exemption (U.S. Food and Drug Administration, 2006).

In 2021, we identified no newly published literature to add to the policy.

In 2022, we added several new large reviews, which reported:

- SynCardia had been implanted in over 2,000 patients; overall one-year survival in patients supported by the device is 42%, and 83% for those who make it to transplant (Henn, 2022).
- Of all 471 total artificial heart implants in the United States from 2015-2018, mortality one year after transplant was 20.0%. Centers that performed fewer than 10 implants were linked with significantly higher mortality on the total artificial heart (P < .001) and post-transplant (P = .039) (Itagaki, 2022).
- Of 433 patients who underwent total artificial heart with SynCardia as a bridge to transplantation, one-year mortality was 20%. The mortality among those on a wait list was 7.4% (Coyan, 2022).

In 2023, we added several reviews:

- A review of 100 recipients of SynCardia implants tracked for a median of 4.6 years showed 61 were successfully bridged to transplantation and 39 died on total artificial heart support. Over half (20 of 39) of the deaths were caused by multisystem organ failure. Survival after transplantation at six months, one year, and five years were 95.1%, 86.6%, and 77.5% (Malas, 2023).
- A review of 75 inpatient total artificial heart patients (U.S.) showed all but one was 70 years or younger. The death rate was 29.3%, and the most common complications were acute renal failure (69.3%) and infections (28.0%) (Pasha, 2022).
- Outcomes for heart transplant patients with a total artificial heart as a bridge to transplantation (n = 392) from 2005-2020 were compared with those with durable left ventricular assist device and de novo heart transplants. The total artificial heart group had higher dialysis dependence (P < .001); lower 10-year survival (P = .04); but similar 10-year survival conditional on one-year survival (P > .20) (Chen, 2022).

In 2024, we found a narrative review (Volod, 2024) and a scoping review (Jimeno-San Martín, 2024) on total artificial hearts, focusing on the SynCardia device. The narrative review (Volod, 2024) reports that over 2,000 patients worldwide have received SynCardia total artificial hearts, with more than 60% successfully bridged to transplantation. Both reviews identify common complications, including thromboembolism, hemorrhage, infection, and organ dysfunction (Volod, 2024; Jimeno-San Martín, 2024). The scoping review (Jimeno-San Martín, 2024), based on 23 documents of predominantly low to very low quality evidence, details postoperative

management practices, emphasizing multidisciplinary care and specialized nursing interventions. Both reviews highlight significant variability in care protocols, particularly regarding anticoagulation, device management, and rehabilitation (Volod, 2024; Jimeno-San Martín, 2024). The reviews concur on the need for high-quality research to standardize care practices and improve outcomes. While acknowledging progress in total artificial heart technology, both reviews indicate persistent challenges with these devices including size limitations, durability concerns, the need for external power sources, infection risks associated with drivelines, and the complexity of managing anticoagulation therapy in patients with total artificial hearts (Volod, 2024; Jimeno-San Martín, 2024). No policy changes warranted.

References

On August 5, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Heart-assist devices” (MeSH), “Heart, artificial” (MeSH), “SynCardia,” “Abiocor,” and “total artificial heart." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

7/2016: initial review date and clinical policy effective date: 10/2016

10/2017: Policy references updated.

8/2018: Policy references updated. Policy ID changed.

9/2019: Policy references updated. Ventricular assist devices removed from policy. Focus on total artificial hearts only.

9/2020: Policy references updated. Abiocor coverage added.

9/2021: Policy references updated.

9/2022: Policy references updated.

9/2023: Policy references updated.

9/2024: Policy references updated.

Appendix

New York Heart Association Functional Classification of Heart Failure:

- Class I. No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
- Class II. Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- Class III. Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (~ up to 300 feet). Comfortable only at rest.
- Class IV. Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

American College of Cardiology Foundation/American Heart Association Stages of Heart Failure (Hunt, 2009):

- Stage 1. At high risk for heart failure but without structural heart disease or symptoms of heart failure.
- Stage 2. Structural heart disease but without signs or symptoms of heart failure.
- Stage 3. Structural heart disease with prior or current symptoms of heart failure.
- Stage 4. Refractory heart failure requiring specialized interventions. Unable to carry on any physical activity without symptoms of heart failure, or symptoms of heart failure at rest.

Interagency Registry for Mechanically Assisted Circulatory Support profiles for classifying patients with advanced heart failure at time of implant (2018):

Profile 1. Critical cardiogenic shock, “crash and burn.”
Profile 2. Progressive decline, on inotropic support or in whom inotropic infusions cannot be maintained due to tachyarrhythmias, clinical ischemia or other intolerance.
Profile 3. Stable but inotrope dependent, or has a temporary circulatory support device after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal).
Profile 4. Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living.
Profile 5. Exertion intolerant living predominantly within the house or housebound.
Profile 6. Exertion limited, comfortable at rest without evidence of fluid overload and able to do some mild activity but easily fatigued with any meaningful physical exertion, and likely to have had a hospitalization for heart failure within the past year.
Profile 7. Advanced New York Heart Association Class III, clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent.

Source: New York Heart Association, 1994