Total artificial heart

Clinical Policy ID: CCP.1250

Recent review date: 9/2025

Next review date: 1/2027

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

First Choice Next has developed clinical policies to assist with making coverage determinations. First Choice Next'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, on a case by case basis, by First Choice Next 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. First Choice Next'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. First Choice Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice Next will update its clinical policies as necessary. First Choice Next'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

The evidence on donor orthotopic heart transplantation, total artificial hearts, and ventricular assist devices is reported across international guidelines, systematic reviews and meta-analyses, registry studies, and single-center series. Guidelines describe total artificial hearts primarily as bridging therapy for patients with advanced biventricular failure and identify limited data on their use as destination therapy (Kirklin, 2020; McDonagh, 2021; National Institute for Health and Care Excellence, 2017; Peura, 2012; Ponikowski, 2016). Systematic reviews and meta-analyses show higher survival and quality of life following donor transplantation, with one year survival consistently near 87% compared with 72–75% for mechanical devices, and five year survival of 75% compared with 50–55% for mechanical devices. Mechanical devices are also associated with survival to transplantation and measurable improvements in quality of life (Ali, 2025; Jimeno-San Martín, 2024; Maynes, 2020; Volod, 2024). Registry studies indicate that outcomes with total artificial hearts vary by patient selection and center volume, with lower survival in older or more comorbid patients and in centers performing fewer implants (Arabía, 2018; Coyan, 2022; Henn, 2022; Itagaki, 2022). Single-center experiences report early mortality on support but also show that patients bridged to transplantation achieve survival at one, five, and ten years consistent with established transplant populations (Malas, 2023; Pasha, 2022; Razumov, 2025; Chen, 2022). Collectively, the evidence indicates that donor transplantation achieves the highest long-term survival, while total artificial hearts and ventricular assist devices demonstrate specific survival, complication, and quality of life outcomes that shape their use in patients not undergoing donor transplantation (Ali, 2025; Volod, 2024)

Clinical guidelines

Guidelines consistently support total artificial hearts only under restricted conditions. The American Association for Thoracic Surgery and International Society for Heart and Lung Transplant identify potential benefit as initial management in advanced right ventricular failure (Kirklin, 2020). The European Society of Cardiology recommends mechanical circulatory support, including total artificial hearts, as bridging therapy for patients at high risk of death while awaiting transplantation (McDonagh, 2021). In contrast, United Kingdom guidance allows implantation only with special arrangements, explicit consent, or within research settings because of limited evidence (National Institute for Health and Care Excellence, 2017). Broader consensus statements emphasize effectiveness in idiopathic and ischemic cardiomyopathy in hospital settings, but stress that safety and efficacy are unproven for destination therapy or outpatient portable drivers (Peura, 2012; Ponikowski, 2016).

Systematic reviews and meta-analyses

Systematic reviews and meta-analyses consistently show that donor transplantation provides the highest survival and quality of life. One synthesis reported one year survival of 87% (95% CI 84–90) with donor transplantation

compared with 75% (95% CI 70–80) for total artificial hearts and 72% (95% CI 68–76) for ventricular assist devices. At five years, survival was 75%, 55%, and 50% respectively. Quality of life scores were also superior with donor transplantation, with Kansas City Cardiomyopathy Questionnaire scores of 85±5 compared with 80±7 for total artificial hearts and 78±8 for ventricular assist devices. Complication profiles differed, with infection rates of 15–35% (pooled 20–25%) and thrombosis around 15% in total artificial heart recipients compared with rejection around 17% and infection around 12% in donor recipients. These findings confirm donor transplantation as the benchmark, while recognizing the role of total artificial hearts and ventricular assist devices as viable options for patients not eligible for donor transplantation (Ali, 2025). A meta-analysis of SynCardia compared with off-label HeartWare biventricular support showed no differences in early bleeding or mortality, though SynCardia recipients had shorter support durations while HeartWare patients were more often discharged home on support (Maynes, 2020). Narrative and scoping reviews emphasize that more than (N = 2,000) SynCardia implants have been performed, with about 60% successfully bridged to transplantation. Persistent challenges include thromboembolism, hemorrhage, infection, and device durability, with wide variation in anticoagulation and management practices (Jimeno-San Martín, 2024; Volod, 2024).

Other studies

Registry and single-center studies deepen understanding of patient outcomes and predictors of survival. An Interagency Registry study of (N = 450) recipients reported survival of 73% at 3 months, 62% at 6 months, and 53% at 12 months, with risk factors including older age, renal dysfunction, hypoalbuminemia, and treatment at centers performing fewer than ten implants (Arabía, 2018). Registry data from (N = 471) recipients between 2015 and 2018 showed one year mortality of 20%, with significantly worse outcomes at lower-volume centers (Itagaki, 2022). A registry analysis of (N = 433) SynCardia recipients bridged to transplantation reported one year mortality of 20% compared with 7.4% among wait-listed patients (Coyan, 2022). A review of (N = 100) SynCardia recipients reported 61 bridged to transplant and 39 deaths, more than half from multiple organ failure, with posttransplant survival of 95.1% at 6 months, 86.6% at 1 year, and 77.5% at 5 years (Malas, 2023). A series of (N = 75) inpatients found mortality of 29.3%, with acute renal failure in 69.3% and infection in 28% (Pasha, 2022). A comparative analysis of (N = 392) patients transplanted after SynCardia bridging reported higher dialysis dependence and lower 10 year survival compared with de novo transplantation or ventricular assist device bridging, though survival conditional on one year was similar (Chen, 2022). Registry-level reviews confirm these trends: in a synthesis of more than (N = 2,000) SynCardia implants, overall one year survival on support was 42% but improved to 83% among those transplanted successfully (Henn, 2022). A 20-year single-center series of (N = 196) SynCardia implants reported survival of 72% at 1 month, 41% at 6 months, and 34% at 12 months. Mortality during support was 64.8%, with multiple organ failure the most common cause of death, but 35.2% were bridged successfully to transplantation. Posttransplant survival was 65% at 1 year, 58% at 5 years, and 51% at 10 years (Razumov, 2025). These results confirm that although early attrition under total artificial heart support remains high, patients who survive to transplantation achieve durable long-term outcomes approaching those of primary transplantation.

In 2025, the findings section was reorganized thematically, with new evidence incorporated from a systematic review and meta-analysis of 20 studies (Ali, 2025) and from a 20-year single-center study of (N=196) SynCardia implants (Razumov, 2025). No policy changes were warranted.

References

On August 5, 2025, 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.

9/2025: 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