Total Artificial Heart

Policy Number:	**M20170427009**
Effective Date:	**6/1/2017**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☐Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☐ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **total artificial heart (TAH)** in members with biventricular **heart failure** as a **bridge to transplantation**.

Policy:

Commercial and Self-Funded:

Bridge to Transplantation (BTT):
There is evidence to support the use of the total artificial heart as a bridge to transplantation in adult patients with biventricular heart failure who:

- are eligible for a heart transplant and
- are at risk of imminent death from biventricular failure **(New York Heart Association NYHA Class IV**).

Use of the total artificial heart is contraindicated in the following patient populations:

- Patients who are not eligible for a heart transplant.
- Patients who do not have sufficient space in the chest area vacated by the natural ventricles. This would typically include patients with BSA < 1.7 m2, or who have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) < 10 cm.
- Patients who cannot be adequately anticoagulated.

Destination Therapy (DT):
Based on peer-reviewed literature, total artificial heart use as destination therapy is considered investigational.

Medicare Advantage:
There is currently a National Coverage Determination (NCD) for total artificial hearts. Please refer to the links listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Essential Plan:
MediSource, MediSource Connect and Essential Plan cover the total artificial heart procedure utilizing the Commercial and Self-Funded criteria above.

Background:
Heart failure is clinical syndrome characterized by symptoms of dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and/or peripheral edema. HF results from a structural or functional impairment of ventricular filling or ejection of blood. The most common cause of HF is ischemic heart disease (coronary artery disease); however, HF may also result from nonischemic heart disease, such as hypertension, valvular heart disease, and cardiomyopathies.

Cardiac transplantation is currently the only proven curative treatment for end-stage heart disease, but the supply of donor hearts has not kept pace with the demand. There are several surgical techniques available which may be employed to maintain heart function or provide a bridge to heart transplantation. In addition, ventricular assist devices and the total artificial heart have been approved by the Food and Drug Administration (FDA) for use as a bridge to transplant in selected persons who are awaiting heart transplantation.

The SynCardia temporary total artificial heart device is a pulsatile total artificial heart which has FDA approval received in 2004 for clinical implantation. This TAH device is currently approved for use as BTT in heart transplant-eligible candidates at risk of imminent death from irreversible biventricular failure and is intended for use inside the hospital. Patients who are implanted with a TAH remain hospitalized for the duration of support (to transplant or death). Post implantation, TAH patients must be placed on anticoagulation protocols to prevent thrombus formation. Patients must be closely monitored to ensure adequate anticoagulation and simultaneously minimize risk of bleeding.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

Bridge to transplantation is a mechanism used to sustain life until a donor organ becomes available.

Destination therapy provides long-term support in patients with refractory heart failure who are ineligible for heart transplantation.

Heart failure is a clinical syndrome characterized by symptoms of dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and/or peripheral edema.

New York Heart Association (NYHA) functional classification system relates symptoms to everyday activities and the patient's quality of life. The functional classifications are as follows:

- Class I (Mild): No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
- Class II (Mild): Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
- Class III (Moderate): Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
- Class IV (Severe): Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

Total artificial heart (TAH) was developed to prolong survival and improve quality of life in maximally medically managed patients with irreversible biventricular heart failure. It consists of a biventricular pulsatile pump that replaces the patient's native ventricles and valves. Implantation of the TAH is performed via a median sternotomy.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

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Health Quality Ontario. Left Ventricular Assist Devices for Destination Therapy: A Health Technology Assessment. Ont Health Technol Assess Ser. 2016 Feb 8;16(3):1-60.

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Regulatory References

Centers for Medicare and Medicaid (CMS). [web site]. National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9). Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=6&DocID=20.9&bc=gAAAABAAAAAAAA%3d%3d& Accessed March 13, 2024.

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New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 5 – Surgery. April 2023. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf Accessed March 13, 2024.

United Stated Food and Drug Administration (FDA) [web site]. Premarket Approval (P030011) Syncardia Temporary Cardio West Total Artificial Heart (TAH-T). Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030011 Accessed March 13, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
5/1/2024	Health Care Services	Revised
1/1/2024	Health Care Services	Revised
5/1/2023	Health Care Services	Revised
5/1/2022	Health Care Services	Reviewed
5/1/2021	Health Care Services	Reviewed
5/1/2020	Health Care Services	Revised
6/1/2019	Medical Management	Revised
6/1/2018	Medical Management	Revised
