

Medical Necessity Guidelines: Temporary Total Artificial Heart System Bridge-to-Transplant

Effective: November 18, 2020

Prior Authorization Required	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	
<p>Applies to: COMMERCIAL Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>TUFTS HEALTH PUBLIC PLANS Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 <p>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p>SENIOR Products</p> <ul style="list-style-type: none"> • Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List • Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List 	

OVERVIEW

The SynCardia FREEDOM[®] driver is for stable Members who meet discharge criteria and can wait for their donor heart at home with the wearable Freedom portable driver which powers the temporary SynCardia Artificial Heart. The Freedom Driver was U.S. FDA Approved June 26, 2014⁴.

The Temporary Total Artificial Heart (TAH-t) functions in place of ventricles and valves by pumping blood to both the pulmonary and systemic circulations. TAH-t is distinguished from prior devices by its portable driver (Freedom driver), a system that powers the device, and is intended for allowing stable Members to recover at home, rather than remain hospitalized while awaiting a Solid Organ Heart Transplant.

Note: Solid organ heart transplantation is a surgical procedure to remove a damaged or diseased heart and replace it with a healthy donor heart. To initiate the prior authorization process for Solid Organ Heart Transplant, refer to the [Solid Organ Transplant: Heart Medical Necessity Guidelines](#).

CLINICAL COVERAGE CRITERIA

Tufts Health Plan may authorize coverage of The SynCardia[™] Temporary Total Artificial Heart (TAH-t) System with the Freedom Portable Driver as a bridge-to-transplant for Members who meet ALL of the following criteria:

- Eligible and approved for a solid organ heart transplant AND currently on a heart transplant list
- At risk for imminent death from biventricular failure
- Able to receive adequate anti-coagulation while on the total artificial heart.
- Member and caregiver(s) have completed the SynCardia Discharge Manual and competencies.

LIMITATIONS

Tufts Health Plan will not cover the use of the SynCardia TAH-t as destination therapy in patients who are not transplant candidates.

CODES

Covered HCPCS/CPT Codes:

Code	Description
0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
Q0480	Driver for use with pneumatic ventricular assist device, replacement only

REFERENCES

1. Hayes Inc. Hayes Search and Summary. SynCardia Total Artificial Heart with the Freedom Portable Driver (SynCardia Systems Inc.) for Bridge to Transplantation in Adults. December 4, 2014. Lansdale, PA: Hayes, Inc.
2. Hayes Inc. Hayes Directory. Total Artificial Heart, Temporary or Permanent, Biventricular Mechanical Circulatory Support Device. May 28, 2015. Lansdale, PA: Hayes, Inc.
3. SynCardia website. SynCardia.com. Accessed January 25, 2015.
4. SynCardia Systems, Inc. Freedom® Driver System Discharge Manual - US
5. U.S. Food and Drug Administration. June 2014 PMA approvals. SynCardia Freedom® Driver System. Accessed January 25, 2015. fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/ucm412361.htm

APPROVAL HISTORY

September 9, 2015: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of January 1, 2016

Subsequent endorsement date(s) and changes made:

- December 9, 2015: Reviewed by IMPAC, renewed without changes
- December 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- November 14, 2018: Reviewed by IMPAC, renewed without changes
- November 20, 2019: Reviewed by IMPAC, renewed without changes
- November 18, 2020: Reviewed by IMPAC, renewed without changes
- December 8, 2020: Fax number for Unify updated

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

[Provider Services](#)