Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Temporary Total Artificial Heart System Bridge-to-Transplant

Effective: January 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

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, 2014[5].

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 Guideline Coverage Criteria

The 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:

1. Eligible and approved for a solid organ heart transplant AND currently on a heart transplant list; **and**
2. At risk for imminent death from biventricular failure; **and**

3. Able to receive adequate anti-coagulation while on the total artificial heart; **and**
4. Member and caregiver(s) have completed the SynCardia Discharge Manual and competencies.

Limitations

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

Codes

The following code(s) are associated with this service:

Table 1: CPT/HCPCS Codes

Code	Description
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)
Q0480	Driver for use with pneumatic ventricular assist device, replacement only

References:

1. Copeland JG, Smith RG, Arabia FA, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med. Aug 26 2004; 351(9): 859-67. PMID 15329423Hayes 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 December 12, 2024.
4. SynCardia Systems, Inc. Freedom® Driver System Discharge Manual – US. https://www.syncardia.com/freedom-portable-driver-system.html. Accessed December 12, 2024.
5. U.S. Food and Drug Administration. June 2014 PMA approvals. SynCardia Freedom® Driver System. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030011S020. Accessed December 12, 2024

Approval And Revision History

November 18, 2020: Reviewed by the Medical Policy Approval Committee (MPAC), renewed without changes

Subsequent endorsement date(s) and changes made:

- December 8, 2020: Fax number for Unify updated
- October 20, 2021: Reviewed by IMPAC, renewed without changes
- October 19, 2022: Reviewed by MPAC. Coding update-removal of code 0051T, addition of replacement codes 33297, 33928, 33929 for Integration purposes between Harvard Pilgrim Health Care and Tufts Health Care
- November 16, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- December 1, 2023: Reviewed and approved by the UM Committee
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025
- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026
- December 8, 2025: Reviewed by UM Committee for annual review, renewed without changes effective January 1, 2026

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. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.