

Effective: September 1, 2023

<p>Prior Authorization Required If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request to the FAX numbers below.</p>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p>Notification Required IF <u>REQUIRED</u>, concurrent review may apply</p>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Applies to:

Commercial Products

- Harvard Pilgrim Health Care Commercial products; 800-232-0816
- Tufts Health Plan Commercial products; 617-972-9409
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
- Tufts Health Unify* – OneCare Plan (a dual-eligible product); 857-304-6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

- Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
- Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
- Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

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

Cardiac transplantation is a treatment for many patients with end-stage heart failure (HF) who remain symptomatic despite optimal medical therapy. A damaged or diseased heart is replaced with a healthy donor heart.

To initiate the prior authorization process, it is necessary to complete and submit the [Heart Transplant Request for Coverage Form](#).

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of a heart transplant for adult and pediatric Members with end-stage heart disease who have satisfactory psychosocial and support systems in place and **ONE** of the following conditions:

1. Congenital heart disease; **or**
2. End stage dilated cardiomyopathy refractory to medical therapy; **or**
3. Ischemic cardiomyopathy refractory to medical therapy and not amenable to revascularization procedures; **or**
4. Myocarditis; **or**
5. Non ischemic cardiomyopathy refractory to medical therapy; **or**

6. Presence of an implanted ventricular assist device; **or**
7. Severely limiting ischemia not amenable to revascularization procedures; **or**
8. Valvular heart disease; **or**
9. Ventricular tachyarrhythmias refractory to all accepted therapeutic modalities

Special Considerations:

Heart-Lung Transplantation:

1. Eisenmenger syndrome with a surgically uncorrectable anomaly and irreversible pulmonary hypertension
2. Pulmonary disease with severe left ventricular failure

Note: A pulmonary diagnosis with severe right heart failure is not an indication for a heart-lung transplant unless accompanied by severe left ventricular failure.

Note: Members >70 years of age may be approved under special circumstances on a case-by-case basis where the Member can be shown to have exceptional pre-morbid performance and has a life expectancy > 5 years. Consideration will occur in the absence of end stage complications of systemic disease such as diabetes mellitus or chronic obstructive lung disease.

Limitations

The Plan will not authorize the coverage of a heart transplant for Members for **ANY** of the following:

1. Active Hepatitis C
2. Active or uncontrolled alcohol use disorder or substance use disorder
3. Any unresolved psychosocial concerns or history of noncompliance with medical management
4. Clinically severe symptomatic cerebrovascular disease or presence of a recent intra-cranial cerebrovascular event with significant persistent deficit(s)
5. Demonstrated non-compliance, which places the transplanted organ at serious risk of failure
6. Fixed pulmonary hypertension:
 - a. Pulmonary vascular resistance > 5 Woods units, unresponsive to medical therapy
 - b. Trans-pulmonary gradient > 15mm/Hg [mean pulmonary artery pressure minus pulmonary capillary wedge pressure]
7. History of malignancy within the past 5 years, including low-grade prostate cancer that has not been ‘cured’ (by prostate-specific antigen measurement), excluding non-melanomatous skin cancers
8. Human immunodeficiency virus (HIV) disease unless **ALL** of the following are met:
 - a. CD4 count >200 cells/μL during 3 months prior to transplantation
 - b. Undetectable HIV-1 ribonucleic acid (RNA)
 - c. Stable anti-retroviral therapy for > 3 months
 - d. Absence of serious complications associated with a secondary to HIV disease, (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Karposi’s sarcoma or other neoplasm)
9. Obesity. Patient’s weight over 130% of ideal (GMI 25-28 to encompass NIH and CDI guidelines) or BMI ≥ 35
10. Recurrent infections; uncontrolled or untreated
11. Systemic illness that will limit survival despite heart transplant such as:
 - a. Systemic lupus erythematosus or sarcoid that has multisystem involvement and is still active
 - b. Any systemic process with a high probability of recurring in the transplanted heart as determined by the requesting physician

Note: Smoking has been strongly correlated to adverse health and surgical outcomes. There is evidence to show that smoking, both by donors and by recipients, has a major impact on outcomes after organ transplantation. Smoking cessation is strongly recommended for both donors and recipients prior to transplantation.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including

Code	Description
	dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

References:

1. Blumberg EA, Rogers CC; American Society of Transplantation Infectious Diseases Community of Practice. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13499. doi:10.1111/ctr.13499.
2. Heart transplantation in adults: UpToDate.com/login [via subscription only]. Published June 15, 2020. Updated July 2021. Accessed August 8, 2021.
3. Mehra MR, Canter CE, Hannan MM, Semigran MJ, Uber PA, Baran DA, Danziger-Isakov L, Kirklin JK, Kirk R, Kushwaha SS, Lund LH, Potena L, Ross HJ, Taylor DO, Verschuuren EAM, Zuckermann A; International Society for Heart Lung Transplantation (ISHLT) Infectious Diseases, Pediatric and Heart Failure and Transplantation Councils. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. J Heart Lung Transplant. 2016 Jan;35(1):1-23. doi:10.1016/j.healun.2015.10.023.
4. Mehra MR, Kobashigawa J, Starling R, et al. Listing criteria for heart transplantation: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. J Heart Lung Transplant. 2006;25(9):1024-1042. doi:10.1016/j.healun.2006.06.008.
5. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J 2016; 37:2129. doi:10.1093/eurheartj/ehw128.
6. The International Society for Heart and Lung Transplantation. Guidance from the International Society of Heart and Lung Transplantation regarding the SARS CoV-2 pandemic. isHLT.org/isHLT/media/documents/SARS-CoV-2_Guidance-for-Cardiothoracic-Transplant-and-VAD-center.pdf. Updated February 1, 2021. Accessed August 12, 2021
7. United Network of Organ Sharing (UNOS) Policies on Organ Sharing (dated 07/27/2021), Retrieved on August 9, 2021 from unos.org.

Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- December 8, 2020: Fax number for Unify updated
- November 17, 2021: Reviewed by IMPAC for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan; under the "Limitations" section changed "CD4 count >200 cells/μL" to "CD4 count >200 cells/μL during 3 months prior to transplantation" and added "Clinically severe symptomatic cerebrovascular disease or presence of a recent intra-cranial cerebrovascular event with significant persistent deficit(s)"
- December 1, 2022: Reviewed by Medical Policy Approval Committee (MPAC), renewed without changes
- March 15, 2023: Reviewed by MPAC, limitations updated to remove smoking cessation and limitation modified from "Active drug, substance abuse, or alcohol abuse within the last 6 months" to "Active or uncontrolled alcohol use disorder or substance use disorder" Effective September 1, 2023

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.