

Medical Necessity Guidelines: Solid Organ Transplant: Heart

Effective: October 21, 2020

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p>Applies to:</p> <p>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 	

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW

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

CLINICAL COVERAGE CRITERIA

Tufts Health Plan may authorize coverage of a heart transplant for adult and pediatric Members with end-stage heart disease and **one or more of the following** conditions:

- Presence of an implanted ventricular assist device
- End stage dilated cardiomyopathy refractory to medical therapy
- Ischemic cardiomyopathy refractory to medical therapy and not amenable to revascularization procedures
- Ventricular tachyarrhythmias refractory to all accepted therapeutic modalities
- Valvular heart disease
- Myocarditis
- Congenital heart disease
- Non ischemic cardiomyopathy refractory to medical therapy
- Severely limiting ischemia not amenable to revascularization procedures
- Satisfactory psychosocial and support systems in place

SPECIAL CONSIDERATIONS

Heart-Lung Transplantation:

- Eisenmenger syndrome with a surgically uncorrectable anomaly and irreversible pulmonary hypertension
- 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 yrs 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

Tufts Health Plan will not authorize the coverage of a heart transplant for Member meeting the following:

- 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
- Recurrent infections; uncontrolled or untreated
- Demonstrated non-compliance, which places the transplanted organ at serious risk of failure
- Active Hepatitis C
- Human immunodeficiency virus (HIV) disease unless **ALL** of the following are met:
 - CD4 count greater than 200 cells/mm³
 - Undetectable HIV-1 ribonucleic acid (RNA)
 - Stable anti-retroviral therapy for > three months
 - Absence of serious complications associated with a secondary to HIV disease, (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm)
- Systemic illness that will limit survival despite heart transplant such as:
 - Systemic lupus erythematosus or sarcoid that has multisystem involvement and is still active
 - Any systemic process with a high probability of recurring in the transplanted heart as determined by the requesting physician
- Fixed pulmonary hypertension:
 - Pulmonary vascular resistance > 5 Woods units, unresponsive to medical therapy
 - Trans-pulmonary gradient > 15mm/Hg [mean pulmonary artery pressure minus pulmonary capillary wedge pressure]
- Any unresolved psychosocial concerns or history of noncompliance with medical management
- Obesity. Patient's weight over 130% of ideal (GMI 25-28 to encompass NIH and CDI guidelines) or BMI ≥ 35
- Active drug, substance, or alcohol abuse within the last 6 months
- Active tobacco use within the last 6 months such as actively smoking cigarettes, or using any nicotine delivery system products (e.g., gum, patches, electronic cigarettes)

CODES

The following HCPCS/CPT code(s) require prior authorization:

Code	Description
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including 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. Colucci, W., Pina, I. Indications and contraindications for cardiac transplantation. UpToDate®. December 2006
2. Costanzo MR, Augustine S, Bourge R et al. Selection and treatment of candidate for heart transplantation. A statement for health professionals from the Committee on Heart Failure and Cardiac Transplantation of the Council on Clinical Cardiology, American Heart Association. Circulation 1995; 92(12):3593-612.
3. Mancini D, Hunt SA, Yeons SB et al. Indications and contraindications for cardiac transplantation. UpToDate®. September 2014.

4. Mudge GH, Goldstein S, Addonizio LJ et al. 24th Bethesda Conference: Cardiac transplantation. Task Force 3: Recipient guidelines/prioritization. J Am Coll Cardiol 1993; 22(1):21-31.
5. Tsai FC, Marelli D, Bresson J et al. Recent trends in early outcome of adult patients after heart transplantation: a single-institution review of 251 transplants using standard donor organs. Am J Transplant 2002; 2(6):539-45.
6. United Network of Organ Sharing (UNOS) Policies on Organ Sharing (dated 6/28/2002), Retrieved on March 1, 2007 from unos.org.

APPROVAL HISTORY

January 2004: Reviewed by the Medical Affairs Medical Policy Committee

Subsequent endorsement date(s) and changes made:

- April 14, 2007: Criteria placed in new format
- April 25, 2008: Reviewed and renewed without changes
- April 6, 2009: Reviewed and renewed without changes
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- November 2010: Reviewed by MCMC. Obesity limitation added. Effective date July 1, 2011.
- December 14, 2011: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes.
- December 12, 2012: Reviewed by IMPAC; no changes
- August 6, 2013: Tobacco use clarified
- December 11, 2013: Reviewed by IMPAC, renewed without changes.
- October 15, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- February 23, 2015: Administrative update.
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- July 20, 2016: Reviewed by IMPAC renewed without changes
- December 13, 2016: Contact information updated
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- July 20, 2017: Reviewed by IMPAC, renewed without changes
- September 18, 2017: Administrative update
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October 2018: Template and disclaimer updated
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- October 21, 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](#)