MEDICAL POLICY

Medical Policy Title	**Heart and Heart-Lung Transplant**
Policy Number	**7.02.06**
Current Effective Date	July 17, 2025
Next Review Date	July 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Heart Transplant

I. Human heart transplantation is considered **medically appropriate** for select adults with end stage heart disease that is unresponsive to any other medical or surgical therapeutic measures and when specific recipient selection criteria have been met.

   A. Acceptable indications for cardiac transplantation include:

      1. For hemodynamic compromise individuals due to heart failure must meet **one** of the following indications:

         a. Maximal oxygen consumption (Vo2) <10ml/kg/min with achievement of anaerobic metabolism;

         b. Refractory cardiogenic shock;

         c. Documented dependence on intravenous inotropic support to maintain adequate organ perfusion;

      2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty; **or**

      3. Recurrent symptomatic ventricular arrhythmias refractory to all accepted therapeutic modalities.

   B. Probable indications for cardiac transplantation include:

      1. Symptomatic heart failure with peak VO2max less than14 ml/kg/min;

      2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; **or**

      3. Instability of fluid balance or renal function not due to the individual's non-compliance with regime of weight monitoring, flexible use of diuretic drugs, and salt restriction.

   C. Inadequate indications for cardiac transplantation include:

      1. Ejection fraction <20% with mild to moderate symptoms;

      2. History of functional class (NYHA Class) III or IV symptoms or transient need for inotropic support on a suboptimal medical regime (see Professional Guidelines section);

3. Previous ventricular arrhythmias that are now controlled;
4. Maximal VO2max greater than 15 ml/kg/min without other indications.

Heart and Lung Transplant

II. Heart-lung transplantation for carefully selected individuals with end-stage cardiac and pulmonary disease that is unresponsive to any other medical or surgical therapeutic measures is considered **medically appropriate** when recipient selection criteria have been met.

A. Acceptable indications for heart-lung transplantation include, but are not limited to the following:

1. Irreversible primary pulmonary hypertension with heart failure;
2. Non-specific severe pulmonary fibrosis;
3. Eisenmenger complex with irreversible pulmonary hypertension and heart failure;
4. Cystic fibrosis with severe heart failure;
5. Chronic obstructive pulmonary disease with heart failure;
6. Emphysema with severe heart failure; **or**
7. Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

B. General contraindications for all solid organ transplantation include, but are not limited to the following:

1. Presence of malignancy (other than non-melanoma skin cancers) unless malignancy has been completely resected or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;
2. Psychosocial instability (e.g., patterns of non-adherence to medical therapies to such a degree that it may jeopardize the success of a transplant);
3. History of ongoing or recent substance abuse (e.g., nicotine addiction);
4. Active peptic ulcer disease;
5. Severe peripheral vascular disease;
6. Other irreversible end stage, life-limiting illness or conditions not attributed to heart or lung disease;
7. Neuromuscular neurological disorder that necessitates chronic placement with no likelihood of improvement.;
8. Systemic disease that could be exacerbated by immunosuppression; **or**
9. Acquired immune deficiency syndrome (AIDS) unless the following are met:

a. CD4 count greater than 200 cells/mm3;

b. HIV-1RNA undetectable;

c. On stable anti-retroviral therapy > three (3) months; **and**

d. Meets all other criteria for transplantation.

C. Heart transplantation is contraindicated for the following indications including, but not limited to:

1. For heart transplantation alone:

a. Pulmonary hypertension;

b. Severe pulmonary disease (an FEV1 of less than 50% predicted) despite optimal medical therapy;

c. Irreversible hepatic dysfunction;

d. Irreversible renal dysfunction.

RELATED POLICIES

Corporate Medical Policy

2.02.55 Laboratory Testing for Transplantation Rejection

7.02.10 Lung and Lobar Lung Transplant

POLICY GUIDELINE(S)

I. Prior authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. Recipient considered for thoracic transplantation will be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

III. Pre-transplant evaluation documentation should include **ALL** the following clinical information. (If testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):

A. Clinical Evaluation:

1. Confirmation of diagnosis;

2. Identification of comorbidities;

3. Treatment of co-morbidities;

4. Current assessment of co-morbidities;

5. Consult notes (if applicable).

B. Psycho-Social Evaluation:
   1. Karnofsky performance score and/or Palliative Performance Scale (PPS) score;
   2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or substance abuse).

C. Oral Health Evaluation

D. Lab Tests:
   1. CBC, metabolic profile;
   2. Serologies: CMV, Hepatitis B and C;
   3. HIV Testing.

E. Cardiac Assessment:
   1. 12 Lead EKG;
   2. Stress (exercise, nuclear, or dobutamine);
   3. Echo or MUGA Scan.

F. Pulmonary Assessment:
   1. Chest x-ray;
   2. Pulmonary function tests (PFTs); for high-risk respiratory failure including but not limited to: COPD, asthma, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history;
   3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).

G. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. [https://uspreventiveservicestaskforce.org/uspstf/] [accessed 2025 May 28]

IV. Transplant reauthorization is required annually while on the transplant waiting list, using the same criteria as pre-testing requirements (See Policy Guideline III). If the individual health condition remains unchanged from the previous year, some testing may be waived. If testing is not performed, a rationale must be provided, and documentation must be dated within the last 11 months, unless otherwise specified (e.g., age-related testing).

DESCRIPTION

A heart transplant involves replacing a diseased heart with a healthy donor heart. It is considered for individuals with end stage heart failure who have not responded to other treatments. Heart transplants are usually indicated for individuals suffering from severe heart disease, congenital heart defects, life threatening arrhythmias not controlled by other therapies, and intractable angina not amenable to revascularization. The combined heart-lung transplantation is intended to prolong

survival and improve function in individuals with end-stage cardiopulmonary or pulmonary disease that have been unresponsive to any other therapies. These procedures are performed on selected individuals with end stage heart and pulmonary disease.

SUPPORTIVE LITERATURE

Heart and heart/lung transplantation represents the only curative approach for carefully screened individuals with end-stage or congenital heart and pulmonary disease. Transplantation is limited due to the profound shortage of donor hearts and lungs.

Sertic et al (2020) compared outcomes of adults diagnosed with Eisenmenger syndrome (ES) who had a heart-lung transplant (HLT) or bilateral lung transplant (BLT) with the repair of a cardiac defect. Information was obtained from the United Network for Organ Sharing (UNOS) database of heart-lung transplantation from 1987 to 2018. During the study period a total of 442 adults with ES had thoracic transplantation (316 HLT and 126 BLT). BLT recipients had a higher median BMI (22.4 kg/m2 vs 21.3 kg/m2), lower bilirubin level at listing (0.8 vs 1.0 mg/dL), and longer wait-list time to receive a transplant (500 vs 336.5 days). Both groups had similar in-hospital mortality following transplant (BLT 27.8% and HLT 26.6%). BLT recipients had significantly longer allograft ischemic time (5.9 vs 3.7), longer hospital stays (32 vs 23 days), and a higher rate of bronchial strictures. Overall survival was similar between patients who underwent double-lung transplantation and those who underwent heart/lung transplantation at 1-year (63.1% vs 68.0%, respectively), 5 years (38.5% vs 47.3%), and 10 years (30.2% vs 30.5%) posttransplant (p=.6). Overall survival did not differ among patients who received transplantation between 1987 to 1999 and those who received transplantation between 2000 to 2018 (p=.7).

Having HIV is no longer an absolute contraindication for transplantation. Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long term survival of HIV positive (HIV+) recipients.

Koval et al (2019) conducted a multicenter retrospective study of heart and lung transplantation outcomes in HIV individuals. There were a total 29 recipients from 14 states. Of the 29 recipient there were 21 heart transplants, seven (7) lung transplants, and one (10 heart-lung transplant reported. The median age was 48 years for heart transplant and 57 years for lung transplant recipients. The median time spent on the wait list was 82 days (range, 9−757) for heart transplant and 42 days (range, 4−200) for lung transplant. Baseline CD4+ T-cell counts were 398 cells/ml for hearts and 536 cells/ml for lungs. Two heart transplant recipients had detectable HIV RNA at time of transplantation all others were transplanted with undetectable HIV viral load. All patients were on a 3-drug antiviral regimen at the time of transplantation. Prior opportunistic infection was present in 6 patients, 2 with multiple significant past infection (e.g., cytomegalovirus (CMV), Pneumo-cystis jirovecii pneumonia, Mycobacterium avium complex, and Mycobacterium tuberculosis infection). Acute cellular rejection (ACR) was reported in 14 of 21 (67%) heart and 2 lung transplants at 1-year post-transplant. Six malignancies were identified during the follow up (5 heart and 1 lung). Two of these cases developed within the first-year post transplantation. Most were non-melanoma skin cancers, but they also included glioblastoma and prostate cancer. Researchers concluded that

thoracic organ transplantation is an effective and feasible treatment option for patients with ES.

PROFESSIONAL GUIDELINE(S)

The New York Heart Association (NYHA) Heart Failure Classification System is a risk stratification tool for heart failure and determines clinical trial eligibility, candidate selection for drugs, devices, and transplants. The NYHA classification system categorizes heart failure severity into four classes based on physical activity limitations and symptoms.

Class I	Individual has cardiac disease but no limitation of physical activity.
Class II	Individual has slight limitation of physical activity. They are comfortable at rest but ordinary physical activity results in fatigue
Class III	Marked limitations of physical activities individuals are countable at rest but less than ordinary activity causes fatigue palpitations or shortness of breath.
Class IV	Symptoms of heart failure at rest (e.g., angina, shortness of breath) and physical activity increases discomfort.

The American College of Cardiology/American Heart Association (ACC/AHA) Guideline for the Management of Hypertrophic Cardiomyopathy (2024) provides the following recommendation for the management of individual with hypertrophic cardiomyopathy. The following are some key recommendations:

- Individuals with Class III -IV symptoms and risk factors for atrial fibrillation (AF) are considered high risk. Annual extended ambulatory rhythm monitoring is recommended in such individuals to detect subclinical AF (Class I recommendation).
- Cardiopulmonary exercise is recommended in advanced heart failure (NYHA Class III-IV) to assess transplant candidacy (class I recommendation)
- Transplant evaluation is recommended in advanced HF or life-threatening arrhythmias refractory to guideline directed medical therapy (Class I recommendation).

The International Society for Heart and Lung transplantation (ISHLT) published updated comprehensive guidelines for the care of heart transplantation recipients building on their 2010 guidance. The 2023 update incorporates new evidence, expanded pediatric considerations, and detailed clinical recommendations across the transplant continuum. The guideline is organized by 4 Task Force teams each focusing on the keys phase or domain of the heart transplantation. The following are some Class I recommendations:

- During the pre-transplant optimization phase frailty should be assessed using the standard tool like the modified Fried criteria.

- A multidimensional nutritional assessment tool should be used to screen for malnutrition or risk thereof.
- Long term mechanical circulatory support is recommended in patients with high-risk features such as inotrope dependency or reversible contraindication.
- In pediatric patients, extracorporeal membrane oxygenation (ECMO) should be used as a bridge to transplant in cases of refractory heart failure.
- Asymptomatic moderate to severe rejection should prompt adjustments of maintenance immunosuppressive therapy.
- Donor hearts with ischemic time greater than 4 hours should only be used under specific favorable conditions.
- All transplant patients should be screened for alcohol tobacco and illicit drug use.
- Live vaccines are contraindicated post-transplant.

REGULATORY STATUS

Solid organ transplants are considered surgical procedures and are therefore not regulated by the Food and Drug Administration (FDA). However, the FDA through its Center for Biologics Evaluation and Research does regulate human cells and tissues intended for implantation transplantation or infusion under code of Federal Regulation Title 21, parts 1270 and 1271. Available from: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products: Small Entity Compliance Guide; Guidance for Industry [accessed 2025 Jun 16]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33944	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to

Code	Description
	prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Not Applicable	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Heart Transplants (NCD 260.9) [accessed 2025 May 28]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

10/18/01, 04/17/02, 07/17/03, 06/17/04, 03/17/05, 02/16/06, 02/15/07, 01/17/08, 03/19/09,

03/18/10, 03/17/11, 03/15/12, 02/21/13, 02/20/14, 02/19/15, 03/17/16, 03/16/17, 03/15/18, 04/18/19, 04/16/20, 04/15/21, 04/21/22, 06/22/23, 07/18/24, 07/17/25	
Date	**Summary of Changes**
07/17/25	• Annual review; policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date