MEDICAL POLICY DRAFT

MEDICAL POLICY DETAILS	
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Product Disclaimer	~~• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*~~ ~~• *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.*~~ ~~• *If a Medicaid product covers a specific service, and there are no New York State guidelines (eMedNY)criteria, medical policy criteria apply to the benefit.*~~ ~~• *If a Medicare 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 product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*** • ***If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Heart Transplant:

A. Improved outcomes in the treatment of heart failure in response to medical therapy, coupled with the critical shortage of donor organs, makes it imperative to restrict heart transplants to patients who are most disabled and are likely to derive the maximum benefit from transplantation. Hemodynamic and functional criteria are helpful in identifying these patients.

Based upon our criteria and assessment of the peer-reviewed literature, heart transplantation for carefully selected individuals with end-stage heart disease that is unresponsive to any other medical or surgical therapeutic

measures has been medically proven to be effective and, therefore, is considered **medically appropriate** when recipient selection criteria have been met.

B. The following are guidelines set forth by the American College of Cardiology (ACC) and the United Network for Organ Sharing (UNOS), which will be utilized in considering recipients for heart transplantation. The following are acceptable, probable and inadequate listing criteria guidelines for potential transplant patients:

A. *Acceptable* indications for cardiac transplantation:
a. Maximal VO_{2max} (peak exercise oxygen consumption) less than 10ml/kg/min with achievement of anaerobic metabolism;
b. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty;
c. Recurrent symptomatic ventricular arrhythmias refractory to ALL therapeutic modalities; and
d. Cardiogenic shock or low output state requiring mechanical or inotropic support.

2. *Probable* indications for cardiac transplantation:
a. Symptomatic heart failure with peak VO_{2max} less than14 ml/kg/min;
b. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; and
c. Instability of fluid balance/renal function not due to patient non-compliance with regime of weight monitoring, flexible use of diuretic drugs, and salt restriction.

3. *Inadequate* indications for cardiac transplantation:
a. Ejection fraction less than 20% with mild to moderate symptoms;
b. History of functional class (NYHA Class) III or IV symptoms or transient need for inotropic support on a suboptimal medical regime;
c. Previous ventricular arrhythmias that are now controlled; and
d. Maximal VO_{2max} greater than 15 ml/kg/min without other indications.

C. UNOS has developed a method for prioritizing patients awaiting donor hearts assuring equitable distribution of organs. The system establishes objective medical urgency status levels that ensure that patients who have the most urgent medical need and have a high likelihood of survival following surgery have the best chance of getting an organ. In 2018, a new 6 tier allocation system was introduced. The levels are 1, 2, 3, 4, 5 and 6 to prioritize the sickest patients with the goal of reducing waitlist mortality. Changes were made to address the increasing number of patients on the transplant waiting list, to better account for the severity of illness, and to reflect for an increasing population of patients being supported with a left ventricular assist device (LVAD). There are separate status criteria for pediatric patients that UNOS updated in 2016. The UNOS Adult Thoracic Organ Status criteria are:

Old allocation system	New allocation system	Listing Criteria
	Status 1	• Venoarterial extracorporeal membrane oxygenation (VA-ECMO), • Nondischargeable, surgically implanted, nonendovascular biventricular support device, • Mechanical circulatory assist device (MCSD) with life-threatening ventricular arrhythmia.

Status 1A	**Status 2**	• Intra-aortic balloon pump (IABP), • Nondischargeable, surgically implanted, nonendovascular left ventricular assist device (LVAD), • Ventricular tachycardia (VT) or ventricular fibrillation (VF) without mechanical support, • MCSD with device malfunction or failure, • Total artificial heart (TAH), BiVAD, RVAD, or VAD for single ventricle patients, • Percutaneous endovascular MCSD.
	Status 3	• Dischargeable LVAD for discretionary 30 days, • Multiple inotropes or single high-dose inotrope with continuous hemodynamic monitoring, • Single inotrope with continuous monitoring, • VA-ECMO after 7 days; IABP or percutaneous endovascular circulatory support device after 14 days • Nondischargeable, surgically implanted, nonendovascular LVAD after 14 days, • Mechanical support device with complication.
Status 1B	**Status 4**	• Dischargeable LVAD without discretionary 30 days, • Inotropes without hemodynamic monitoring, • Retransplant, • Diagnosis of CHD, ischemic heart disease with intractable angina, hypertrophic cardiomyopathy (CM), restrictive CM, amyloidosis.
Status 2	**Status 5**	• On waitlist for at least one other organ at the same hospital.
	Status 6	• All other active candidates

II. Heart-Lung Transplant:

Based upon our criteria and assessment of the peer-reviewed literature, *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 has been medically proven to be effective and, therefore, is considered **medically appropriate** when recipient selection criteria have been met.

The diagnoses appropriate for consideration for heart-lung transplantation include but are not limited to:

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; and
7. Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

III. Recipient Selection Guidelines:

Each individual 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

patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

IV. Relative contraindications to heart or heart lung transplantation include, but are not limited to:
- A. For heart transplantation alone:
  1. Pulmonary hypertension; and
  2. Severe pulmonary disease (an FEV_1 of less than 50% predicted) despite optimal medical therapy;
- B. Irreversible hepatic dysfunction;
- C. Irreversible renal dysfunction;
- D. Systemic infection making immune suppression unsafe including but not limited to, hepatitis b virus, cytomegalovirus (positive donor to a negative recipient), and HIV infection unless ALL of the following criteria are met:
  1. CD4 count greater than 200 cells/mm^3;
  2. HIV-1RNA undetectable;
  3. On stable anti-retroviral therapy greater than three months;
  4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
  5. Meets all other criteria for transplantation
- E. Psychosocial instability - a pattern of non-adherence to medical therapies to such a degree that it may jeopardize the success of a transplant;
- F. Neuromuscular neurological disorder that necessitates chronic placement with no likelihood of improvement;
- G. 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;
- H. Other life-limiting illness or conditions;
- I. History of ongoing or recent substance abuse; including nicotine addiction;
- J. Active peptic ulcer disease; and
- K. Severe peripheral vascular disease.

POLICY GUIDELINES

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

II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing ~~should~~ **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.
  2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).
- C. Dental Evaluation.
- D. Lab Tests:
  1. CBC, metabolic profile;
  2. Serologies: CMV,
  3. Hepatitis B and C;
  4. HIV Testing.
- E. Cardiac Assessment:

1. 12Lead EKG;
2. **Stress (exercise, nuclear, or dobutamine), echo** or MUGA Scan.

F. Pulmonary Assessment:
1. Chest x-ray;
2. Pulmonary function tests (PFTs).
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/recommendation-topics

~~1. Age greater than or equal to 45 years:~~
~~a. Colonoscopy (within 10 years); or~~
~~b. Flexible sigmoidoscopy (within five years); or~~
~~c. Guaiac stool testing (within one year); or~~
~~d. Rationale of contraindication to testing (if applicable).~~
~~2. Women age 21-70 years:~~
~~a. Pap smear (within three years).~~
~~3. Women age greater than or equal to 40 years:~~
~~a. Mammogram (within two years).~~

III. Re-authorization

Transplant re authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past eleven months (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation).

A. Clinical Evaluation:
1. **Updated list of diagnoses to include identification of comorbidities, current assessment and treatment plan.**
2. **Applicable specialty consultation notes**

B. Current functional ability as evidence by current Karnofsky performance score (KPS); and/or Palliative Performance Scale (PPS) score.

C. Follow- up Dental Evaluation

D. Lab Tests: Unless clinically contraindication
1. **CBC, metabolic profile;**
2. **Serologies: CMV;**
3. **Hepatitis B and C; and HIV testing**

E. Cardiac Assessment:
1. **12 Lead EKG; and**
2. **Stress (exercise, nuclear, or dobutamine), echo or MUGA Scan (If applicable).**

F. Pulmonary Assessment:
1. **Chest x-ray;**
2. **Pulmonary function tests (PFTs) (If applicable)**
3. **Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 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/recommendation-topics

DESCRIPTION

A heart transplant involves replacing a diseased heart with a healthy donor heart. The combined heart-lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiopulmonary or pulmonary disease that have been unresponsive to any other therapies. These procedures are performed on *selected* patients with end stage heart and pulmonary disease.

RATIONALE

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

Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long term survival.

Solid organ transplantation for candidates who are HIV positive (HIV+) has long been controversial, due to the long-term prognosis for HIV positivity, and the impact of immunosuppression on HIV disease. Although HIV+ transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients consist primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease. Furthermore, UNOS has stated its position that asymptomatic HIV+ patients should not necessarily be excluded for candidacy for organ transplantation: "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy." In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant, unless the specific criteria listed in this policy regarding HIV status and heart transplants have been met.

According to the United Network for Organ Sharing (UNOS) 2023, wait times for transplants vary, and not everyone who needs a transplant will get one because of the shortage of organs that are suitable for donation. Only slightly more than 50% of people on the waiting list will receive an organ within five years. After the initial transplant evaluation, it is recommended that the awaiting transplant recipient work closely with their transplant team to remain active recipient on a transplant waiting list.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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

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HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
Various	

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*Key Article

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Heart Transplants. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=112&ncdver=3&bc=AgAAgAAAAAAA&