Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Frequently Revision:
Heart and Lung Transplantation	**MP-SU-FP-05-25**	☒ **MMM MA** ☒ **MMM MultiHealth**	**08/22/2025** **Last Review Date:** **08/22/2025**	**Annual** **Page: 1 of 7**

Service Category:

☐ Anesthesia
☒ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☐ Other: _____

Service Description:

Heart-lung transplantation is a complex surgical procedure for patients with end-stage heart and lung disease unresponsive to medical treatment. It involves replacing both organs from a single donor and aims to improve survival and quality of life. Candidates undergo a comprehensive multidisciplinary evaluation. The procedure is performed in accredited transplant centers and requires strict postoperative care, including immunosuppression and monitoring for possible complications.

Background Information:

Heart and lung transplantation (HLTx) represents a therapeutic option for patients with end-stage cardiopulmonary failure in whom isolated heart or lung transplantation is not feasible due to the severity or interdependence of both organ dysfunctions. Although Heart and lung transplantation (HLTx) is performed less frequently than isolated heart or lung transplants, it remains a critical intervention for a highly selected patient population with complex pathophysiology, such as those with congenital heart diseases associated with pulmonary vascular disease, Eisenmenger syndrome, or severe pulmonary arterial hypertension with right heart failure [1]. As noted by Le Pavec et al. (2018), Heart and lung transplantation (HLTx) remains a demanding but vital procedure within the transplant landscape, offering the only viable solution for some patients with complex cardiopulmonary disease for whom no alternative therapy exists. Continued research and clinical innovation are necessary to address the unique immunologic and functional challenges posed by this dual-organ transplant.

Indications include conditions such as pulmonary hypertension, congenital heart defects with severe lung involvement, and advanced interstitial lung disease. According to the International Society for Heart and Lung Transplantation (ISHLT), the process includes a comprehensive multidisciplinary evaluation to confirm the patient's clinical, psychosocial, and functional eligibility. Once approved, the candidate remains on the waiting list until a compatible donor is identified. Subsequently, surgery is performed, and strict postoperative follow-up begins, with emphasis on immunosuppression, rehabilitation and control of possible complications. The procedure involves replacing both the heart and lungs with those from a single donor, offering the potential to prolong survival and improve quality of life. However, heart and lung transplantation carry significant risks, such as organ rejection, infection, and complications related to immunosuppressive therapy, making it a challenging but life-saving intervention [1,2].The primary goal of this service is to improve the quality of life and increase survival for patients with advanced heart and lung disease by providing access to highly specialized therapy at accredited transplant centers that must meet the requirements of 42 CFR, chapter 1, Subchapter K, § 121.9 [3].

The Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation (ISHLT) issued a 2021 updated consensus document for the selection of heart-lung transplant candidates. The authors include the following information [3]:

> Candidates should meet the criteria for lung transplant listing and have significant dysfunction of one or more additional organs or meet the listing criteria for a non-pulmonary organ transplant and have significant pulmonary dysfunction.
>
> The primary indication for heart-lung transplantation is pulmonary hypertension, either secondary to idiopathic pulmonary arterial hypertension or congenital heart disease (CHD). Criteria for heart-lung transplant listing described in a previous version of this document include the presence of New York Heart Association (NYHA)

functional class IV symptoms despite maximal medical management, a cardiac index below 2 l/min/m^2, and a mean right atrial pressure above 15 mmHg; however, the decision about whether to list a patient for heart-lung transplant remains difficult. The estimated number of people in NYHA ACC/AHA stage D or NYHA class IV is 15,600 to 156,000. Heart transplantation in patients with an inadequate response to medical treatment has been shown to prolong survival and improve quality of life [12].

Heart-lung and other multi-organ transplantation should be limited to centers with experience in such procedures and where specialists are available to manage each of the transplanted organs.

Leard et al., describe multiple risk factors for lung transplantation and Peled, Y., et al, mentions the potential and/or relative contraindications of heart transplantation. Based on Table 2 [3] Risk factors for poor post-transplant outcomes. The following categories are established: Absolute contraindications, Potential and or Relative contraindications: and Risk factors with unfavorable implications in the short and long term. Acceptable in high-experience programs, but multiple together increased risk [3] These are listed in the Limitations and Restrictions section.

A comprehensive assessment includes assessment of lung disease severity, anatomy, nutritional status, degree of frailty, presence and severity of comorbidities, psychosocial circumstances, and health-related behaviors that affect recovery and long-term survival. The timing of complete evaluation for transplantation should be based on transplant providers' assessment of potentially modifiable risk factors for transplantation, the patient's disease trajectory, and the likelihood of prolonged waiting for suitable donor organs [10].

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Medical Necessity Guidelines:

Transplantation is considered medically necessary when there is progressive, symptomatic, and irreversible functional failure, and when transplantation is expected to improve survival and quality of life compared to standard medical treatment. Medical necessity is closely related to the comprehensive evaluation of the patient, which includes cardiopulmonary, functional, psychosocial, and nutritional aspects (Le Pavec et. al, 2018). The decision must be supported by a multidisciplinary team with transplant experience and in accordance with the selection criteria established by organizations such as the International Society of Heart and Lung Transplantation.

Heart/lung transplantation is considered **medically necessary** when the following clinical indications **and** the general individual selection criteria listed below are met.

A. Documentation of clinical indications about dual organ failure requiring heart-lung transplantation. You must comply with one of the following and B and C.

1. Primary pulmonary arterial hypertension with refractory right heart failure: Patients with severe pulmonary hypertension who do not respond to medical treatments and have significant right ventricular failure [1, 10] or;
2. Interstitial lung diseases or chronic obstructive pulmonary diseases (COPD) with significant cardiac dysfunction: when advanced lung diseases coexist with heart failure that cannot be treated with isolated transplants. [10] or;
3. Eisenmenger syndrome due to complex congenital heart disease: Patients with congenital heart disease who have developed irreversible pulmonary hypertension and right ventricular dysfunction [13].

B. Candidate Evaluation complies with all the following [9 -10, 12]:

1. The severity of lung disease
2. Cardiac and pulmonary anatomy
3. Nutritional status
4. The degree of embrittlement
5. The presence and severity of comorbidities
6. Psychosocial circumstances
7. Health-related behaviors that affect recovery and long-term survival.

C. General Individual Selection Criteria:

The patient must not have any absolute contraindication for solid organ transplantation, as outlined by the American Society of Transplantation (AST) in its "Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation" (2001) (4). These are detailed in the section Limitations and Restrictions [15].

Limits or Restrictions:

Facility Requirements:

1. Heart transplantation is covered by Medicare when it is performed at a Medicare-approved facility that meets institutional coverage criteria [14].
2. All organ transplant programs must be in a hospital that has an agreement with a Medicare provider. In addition to meeting the transplant CoPs, the transplant program must also meet the hospital's CoPs [7].

Donor and Recipient Factors:

1. Surgical and postoperative complexity: The procedure is technically demanding, and patients require intensive immunosuppression and close monitoring of complications such as rejection and primary graft dysfunction [9-10].
2. High pulmonary vascular resistance: Pulmonary vascular resistance greater than 5 Wood's units increases the risk of graft failure and postoperative mortality [4, 10]
3. History of previous thoracic surgery: The resulting adhesions and anatomical alterations can complicate the surgical procedure and increase the risk of complications [10].
4. Donor and recipient body size: A significant discrepancy in size may impede transplant viability due to spatial limitations in the chest cavity [8, 10]

Absolute contraindications: Candidates who should not be included in the list, except in exceptional circumstances:

1. Unwillingness or adherence to transplantation [10].
2. Neoplasms at high risk of recurrence or death [10].
3. Glomerular filtration < 40 mL/min/1.73 m² [10].
4. Acute coronary syndrome or myocardial infarction within the past 30 days [10].
5. Cirrosis hepática con hipertensión portal o disfunción sintética [6].
6. Acute kidney failure requiring dialysis [10].
7. Active TB infection or HIV with detectable viral load [10-11].
8. Active substance abuse without evidence of remission [9-10,12].

Potential and or Relative contraindications: Risk factors with substantial increased risk, only considered in centers with experience; Optimize before listing:

1. Age > 70 years [10,12].
2. Coronary artery disease requiring peritransplant surgical bypass [10].
3. Left ventricular ejection fraction < 40% [10].
4. Obesity: IMC > 35 kg/m² by < 16 kg/m² [10,12].
5. Limited performance status with rehabilitation potential [10].
6. Severe hematologic disorders or infectious comorbidities (e.g., Mycobacterium abscesses) [10].
7. Inadequate psychological or social support. [10,12].
8. Severe cerebrovascular disease [12]

Risk factors with unfavorable implications in the short and long term. Acceptable in high-experience programs, but multiple together increased risk:

1. Age 65–70 years [10].
2. Glomerular filtration rate 40–60 mL/min/1.73 m² [10].
3. Revascularized coronary artery disease [10].
4. Connective tissue diseases (e.g., scleroderma) [10].
5. Moderate obesity (BMI 30–34.9 kg/m²) [10].
6. Mild-moderate pulmonary hypertension [10].
7. Previous virus infection with undetectable payload [10].
8. prolonged use of high-dose corticosteroids (CS) [10].

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Codes Information:

ICD-10 Diagnostic Codes:

Codes	Description
Z94.3	Heart and Lung Transplant Status

HCPCS Codes:

Codes	Description
S2054	Multivisceral organ transplantation
S2055	Multivisceral organ extraction from donors, with preparation and maintenance of allografts; From the deceased donor
S2060	Lobar lung transplant
S2061	Donor (lung) lobectomy for transplant, living donor

CPT Codes:

Codes	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 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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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Superseded	MP-SU-FP-05-25 This policy supersedes MP-HLT-FP-08-23 and represents a complete revision reflecting current best practices in heart-lung transplantation as guided by ISHLT, CMS, and peer-reviewed evidence.	Not Required	**08/22/2025**