

Service Description

This policy addresses heart and lung (heart/lung) transplantation criteria for those who have both cardiac (heart) and lung disease.

Heart-lung transplantation is the procedure of choice for selected patients with concomitant end-stage heart failure and end-stage lung disease. Combined heart and lung transplantation is limited to patients in whom it offers the only surgical option for their end-stage cardiac and pulmonary disease. The procedure of choice for pulmonary parenchymal and vascular diseases in the absence of left heart dysfunction is single or double lung transplantation.

During a heart-lung transplant, a donated heart and pair of lungs are taken from a recently deceased donor and are used to replace the patient's diseased heart and lungs.

The most common indication for heart-lung transplantation is complex congenital heart disease with Eisenmenger syndrome (systemic-to-pulmonary communication, pulmonary arterial disease causing severe pulmonary hypertension, and cyanosis). Heart-lung transplant is also infrequently indicated in patients with concomitant end-stage pulmonary disease (eg, idiopathic pulmonary arterial hypertension [IPAH] or cystic fibrosis) **and** either right ventricular failure with objective evidence of right ventricular fibrosis or infarction or refractory left ventricular failure.

For multi-organ transplant requests, criteria must be met for each organ requested.

Cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

Please refer to the following medical policies for specific criteria per type of organ transplant.

- Heart Transplant Medical Policy: MP-HT-FP-01-23
- Lung Transplant Medical Policy: MP-LT-FP-07-23

Please note that all services described in this policy require prior authorization.

- Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
- Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
- Providers must submit all required and requested documentation for case evaluation and determination.
- The plan may request additional documentation and information not received and or provided initially related to condition and diagnosis for case evaluation and determination.
- Any additional documentation submitted specifying medical necessity criteria and considered important for case evaluation and determination will be reviewed by Clinical Team utilizing guidelines and regulation criteria.

Medical Necessity Guidelines

Heart-Lung Transplant may be medically necessary for individuals with end stage cardiac and pulmonary disease, including but not limited to the following diagnoses:

Lung and heart-lung diagnosis categories	Lung and heart-lung diagnoses
Congenital Disease	Eisenmenger's Syndrome: Arterial Septal Defect Eisenmenger's Syndrome: Ventricular Septal Defect Eisenmenger's Syndrome: Multiple Congenital Anomalies Eisenmenger's Syndrome: Patent Ductus Arteriosus Eisenmenger's Syndrome: Other Specify Congenital: Other Specify
Emphysema/COPD	Emphysema/COPD
Cystic Fibrosis	Cystic Fibrosis
Idiopathic Pulmonary Fibrosis	Idiopathic Pulmonary Fibrosis
Primary Pulmonary Hypertension	Primary Pulmonary Hypertension
Alpha-1-Antitrypsin Deficiency	Alpha-1-Antitrypsin Deficiency
Retransplant/Graft Failure	Lung Retransplant/Graft Failure: Obliterative Bronchiolitis Lung Retransplant/Graft Failure: Other Specify Lung Retransplant/Graft Failure: Non-Specific Lung Retransplant/Graft Failure: Acute Rejection Lung Retransplant/Graft Failure: Primary Graft Failure Lung Retransplant/Graft Failure: Restrictive
Other	Sarcoidosis Lung Disease Bronchiectasis

		Pulmonary Fibrosis Lymphangioleiomyomatosis Obliterative Bronchiolitis (Non-Retransplant) Pulmonary Vascular Disease Occupational Lung Disease Inhalation Burns/Trauma Rheumatoid Disease	
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In addition to having one of the clinical indications above, the member must not have a contraindication, as defined by the American Society of Transplantation in *Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation* (2001) listed below.

Absolute Contraindications – for Transplant Recipients include, but are not limited to, the following:

- A. Metastatic cancer;
- B. Ongoing or recurring infections that are not effectively treated;
- C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery;
- D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured;
- E. Active, systemic lupus erythematosus or sarcoid with multisystem involvement;
- F. Any systemic condition with a high probability of recurrence in the transplanted heart;
- G. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations;
- H. Potential complications from immunosuppressive medications are unacceptable to the patient;
- I. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention [CDC] definition of CD4 count, 200cells/mm³) unless the following are noted:
 - 1. CD4 count greater than 200 cells/mm³ for greater than 6 months;
 - 2. HIV-1 RNA undetectable;
 - 3. On stable anti-retroviral therapy greater than 3 months;
 - 4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi’s sarcoma or other neoplasm);
 - 5. Meeting all other criteria for heart-lung transplantation.

For multi-organ transplant requests, criteria must be met for each organ requested.

Cases will be reviewed on an individual basis for coverage determination to assess the member’s candidacy for transplantation.

Limits or Restrictions

Medicare will “cover heart-lung transplants for beneficiaries with progressive end-stage cardiopulmonary disease when they are provided in a facility that has been approved by Medicare for both heart and lung transplantation.

All organ transplant programs must be located in a hospital that has a Medicare provider agreement. In addition to meeting the transplant CoPs, the transplant program must also comply with the hospital CoPs (specified in 42 CFR §482.1 through §482.57).

Reference Information

American Heart Association Classes and Stages of Heart Failure

Link: <https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure>

Centers for Medicare and Medicaid Services (CMS) Transplant Program Requirements

Link: <https://www.cms.gov/medicare/health-safety-standards/certification-compliance/transplant>

CMS

Medicare Coverage Database (MCD)

Link: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx>

Organ Procurement & Transplantation Network (OPTN) Link: <https://optn.transplant.hrsa.gov/>

Steinman, Theodore, et al. Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation. Transplantation. Vol. 71, 1189-1204, No. 9, May 15, 2001.

United Network for Organ Sharing (UNOS). Policy 6 Organ Distribution: Allocation of Hearts and Heart-Lungs. Updated 12/13/2023. Link: <http://optn.transplant.hrsa.gov/governance/policies/>

Policy History

Date	Version	Comments
12/07/2023	Draft	New Medical Policy
12/15/2023	Final	Approved by Medical Policy Committee