Healthy Blue

Medical Policy

Subject:	Heart/Lung Transplantation		
Policy #:	TRANS.00026	**Publish Date:**	12/16/2020
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Description/Scope

This document addresses heart and lung (heart/lung) transplantation criteria for individuals who have both cardiac (heart) and lung disease. A heart/lung transplant refers to the harvesting of one or both lungs and the heart from a single cadaver donor, which is then implanted into a single recipient in a coordinated surgical procedure.

Position Statement

Medically Necessary:

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

Clinical Indications - Individuals must meet **one** of the following criteria:

1. Irreversible primary pulmonary hypertension with heart failure; **or**
2. Secondary pulmonary hypertension and resulting heart failure due to pulmonary fibrosis, cystic fibrosis, chronic obstructive pulmonary disease or emphysema; **or**
3. Eisenmenger's complex or other types of congenital heart disease with irreversible pulmonary hypertension and heart failure.

Investigational and Not Medically Necessary:

A heart/lung transplantation is considered **investigational and not medically necessary** when the above criteria are not met.

Note: For multi-organ transplant requests, criteria must be met for each organ requested. In those situations, an individual may present with concurrent medical conditions which would be considered an exclusion or a comorbidity that would preclude a successful outcome, but would be treated with the other organ transplant. Such cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

General Individual Selection Criteria

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/mm^3) unless the following are noted:
    1. CD4 count greater than 200 cells/mm^3 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.

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.

Rationale

Heart/lung transplantation is a standard treatment for individuals who meet the Medical Necessity criteria listed in this document. Combined heart/lung transplants are reserved for candidates in whom either a heart transplant or a lung transplant alone would not improve the individual's condition and chances of survival.

The Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation issued a 2014 updated consensus document for the selection of heart-lung transplant candidates. The authors (Weill and colleagues, 2015) include the following information:

> Patients with advanced cardiac and lung disease not amenable to either isolated heart or lung transplant may be candidates for combined heart-lung transplantation. Most commonly, patients with irreversible myocardial dysfunction or congenital defects with irreparable defects of the

valves or chambers in conjunction with intrinsic lung disease or severe PAH are considered for heart-lung transplantation.

In 2018, the American Heart Association/American College of Cardiology published guidelines for the management of adults with congenital heart disease (CHD). Typically CHD is treated with simultaneous heart-lung transplantation for conditions that result in irreversible pulmonary hypertension such as Eisenmenger syndrome (Stout, 2019).

In September 2020 the United Network of Organ Sharing (UNOS) reported 44 candidates currently on the active waiting list for heart-lung transplant, up from 15 candidates in 2015. A total of 45 combined heart-lung transplants occurred in 2019. According to the 2016 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients, the 2008 unadjusted survival rates reported at 3 months, 1, 5 and 10 years post-transplant were 86%, 81%, 45% and 29%. In May 2005, the lung allocation score (LAS) was implemented by the Organ Procurement and Transplantation Network (OPTN). This new score changed lung allocation from a system based on waiting time to an algorithm based on the probability of survival for 1 year on the transplant list and survival 1 year post-transplantation. In the last decade the number of lung transplants has significantly increased while the number of heart-lung transplants remains low. Despite the decreasing historical trend, heart-lung transplantation remains as a treatment option for carefully selected individuals with end-stage heart and lung diseases.

Background/Overview

Combined heart-lung transplantation is intended to prolong survival and improve function in individuals with end-stage cardiopulmonary or pulmonary disease. The technique involves a coordinated triple operative procedure, consisting of procurement of a single donor heart-lung block, excision of the heart and lungs of the recipient, and implantation of the new donor heart and lungs into the recipient.

The limiting factor for heart-lung transplantation is the short supply of donor organs. The procurement and distribution of heart-lung organs for transplantations in the United States is under the discretion of the United Network for Organ Sharing (UNOS). A national database of transplant candidates, donors, recipients, and donor-recipient matching and histocompatibility is maintained by UNOS. According to UNOS, the LAS can be used to estimate each transplant candidate's severity of illness and expected post-transplant survival. Clinical information including a candidate's diagnosis and test results are used to calculate an LAS that ranges from 0-100. A lung transplant candidate with a higher LAS will receive higher priority for a compatible lung offer in the same geographic zone. Modifications to the LAS system were last implemented in November 2017. The new LAS calculation is mostly comprised of variables already reported by transplant programs.

Definitions

End-stage heart failure: In people with heart failure, the body does not receive an adequate supply of oxygen. As a result, they can feel weak, fatigued or short of breath. Everyday activities such as walking, climbing stairs, carrying

groceries and yard work can become quite difficult. In end-stage heart failure, the heart is so weakened the individual will die without a heart transplant.

Heart/Lung transplant: Removal of an individual's heart and lungs and replacing it with a heart and lungs from a single donor.

New York Heart Association (NYHA) definitions:

- Class III. Individuals with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea (difficulty breathing) or anginal (chest) pain.
- Class IV. Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort and/ or dyspnea. Symptoms of heart failure or anginal (chest) pain may be present even at rest. If any physical activity is undertaken, cardiac symptoms are increased.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time for service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary, when criteria are met:

CPT	
00580	Anesthesia for heart transplant or heart/lung transplant
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
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
ICD-10 Procedure	
02YA0Z0	Transplantation of heart, allogeneic, open approach
02YA0Z1	Transplantation of heart, syngeneic, open approach
0BYM0Z0	Transplantation of bilateral lungs, allogeneic, open approach
0BYM0Z1	Transplantation of bilateral lungs, syngeneic, open approach
ICD-10 Diagnosis	
	All diagnoses

When services are Investigational and Not Medically Necessary:

For the procedure codes listed above when criteria are not met, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

References

Peer Reviewed Publications:

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4. Ganesh JS, Rogers CA, Bonser RS, et al. Steering Group of the UK Cardiothoracic Transplant Audit. Outcome of heart-lung and bilateral sequential lung transplantation for cystic fibrosis: a UK national study. Eur Respir J. 2005; 25(6):964-969.
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7. Moffatt-Bruce SD, Karamichalis J, Robbins RC, et al. Are heart-lung transplant recipients protected from developing bronchiolitis obliterans syndrome? Ann Thorac Surg. 2006; 81(1):286-291.
8. Pierson RN 3rd, Barr ML, McCullough KP, et al. Thoracic organ transplantation. Am J Transplant. 2004; 4 Suppl 9:93-105.
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10. Trulock EP. Lung transplantation for primary pulmonary hypertension. Clin Chest Med. 2001; 22(3):583-593.
11. Trulock EP, Edwards LB, Taylor DO, et al. The Registry of the International Society for Heart and Lung Transplantation: twenty-first official adult lung and heart-lung transplant report - 2004. J Heart Lung Transplant. 2004; 23(7):804-815.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Hunt SA, Abraham WT, Chin MH, et al. 2009 focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Chronic Heart Failure in the Adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2009; 119(14):e391-e479. Available at: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.109.192065. Accessed on October 1, 2020.
2. Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to update the 2001 Guidelines for the Evaluation and Management of Heart Failure). Circulation. 2005; 112(12):e154-e235. Available at: http://circ.ahajournals.org/content/112/12/e154.full.pdf+html. Accessed on October 1, 2020.

3. Steinman TL, Becker BN, Frost AE, et al. Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001; 71(9):1189-1204.
4. Stout KK, Daniels CJ, Valente AM, Van Hare GF. Clinical practice guideline. 2018 AHA/ACC Guideline for the management of adults with congenital heart disease. J Amer Coll Cardiol. 2019; 73(12):e81-e192.
5. United Network for Organ Sharing (UNOS). Policy 6 Organ Distribution: Allocation of Hearts and Heart-Lungs. Updated September 10, 2020. Available at: http://www.unos.org/. Accessed on October 1, 2020.
6. United States Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. OPTN/SRTR annual report: thoracic organ transplantation. Updated 2016. Available at: https://srtr.transplant.hrsa.gov/annual_reports/Default.aspx. Accessed on October 1, 2020.
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Websites for Additional Information

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Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background, References and Websites sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale, References and Websites sections.
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Reviewed	02/02/2017	MPTAC review. Updated formatting in Position Statement section. Updated References and Websites sections.

Revised	02/04/2016	MPTAC review. Reformatted investigational and not medically statement. Defined abbreviation in investigational and not medically necessary absolute contraindication section. Updated Rationale, Background and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Description, Rationale, References and Websites sections.
Reviewed	02/13/2014	MPTAC review. Updated Description, Definitions, References and Web Sites sections.
Reviewed	02/14/2013	MPTAC review. Rationale, Definitions, and Websites Updated.
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Reviewed	02/17/2011	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References and Websites.
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Revised	03/08/2007	(MPTAC) review. Criteria clarified. References, web sites and coding updated.
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Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	11/15/2001	TRANS.00006H Archived	Heart/Lung Transplant
WellPoint Health Networks, Inc.	09/23/2004	7.04.01	Heart/Lung Transplantation