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# MEDICAL POLICY – 7.03.08 Heart/Lung Transplant

BCBSA Ref. Policy:	7.03.08		
Effective Date:	Nov. 1, 2024	RELATED I	MEDICAL POLICIES:
Last Revised:	Oct. 7, 2024	7.03.07	Lung and Lobar Lung Transplant
Replaces:	Extracted from	7.03.09	Heart Transplant
	7.03.509		

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## Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a heart/lung may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

#### **Policy Coverage Criteria**

Transplant	Medical Necessity
Heart/lung transplant	<ul> <li>Heart/lung transplantation may be considered medically necessary for carefully selected individuals with end-stage cardiac and pulmonary disease including, but not limited to, one of the following diagnoses:</li> <li>Chronic obstructive pulmonary disease with heart failure</li> <li>Cystic fibrosis with severe heart failure</li> <li>Eisenmenger complex (see Definition of Terms) with irreversible pulmonary hypertension and heart failure</li> <li>Emphysema with severe heart failure</li> <li>Irreversible primary pulmonary hypertension with heart failure</li> <li>Nonspecific severe pulmonary fibrosis, with severe heart failure</li> <li>Rulmonary fibrosis with uncontrollable pulmonary hypertension</li> </ul>
	or heart failure
Heart/lung	Heart/lung retransplantation after a failed primary heart/lung
retransplantation	transplant may be considered medically necessary in
	individuals who meet criteria for heart/lung transplantation.

Transplant	Investigational
Heart/lung transplant	Heart/lung transplantation is considered investigational in all other situations not outlined above.

#### **Documentation Requirements**

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

• Office visit notes that contain the relevant history and physical documenting the individual has end stage cardiac and pulmonary disease with the presence of one of the listed diagnoses.

## Coding

Code	Description
СРТ	



Code	Description
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
HCPCS	
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre and posttransplant care in the global definition
<b>Note:</b> CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS	

codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## **Related Information**

## **Definitions of Terms**

**Eisenmenger complex:** A congenital condition associated with ventricular septal defect and pulmonary artery hypertension and eventually pulmonary vascular obstructive disease resulting in the reversal of a "left to right "shunt to the occurrence of a "right to left" shunt. This "right to left" shunting, in which blood flows from the right ventricle into the left ventricle, increases blood flow back to the lungs leaving organs and tissues of the rest of the body poorly oxygenated.

## Heart/Lung-Specific Criteria

When the candidate is eligible to receive a heart in accordance with United Network for Organ Sharing (UNOS) guidelines for cardiac transplantation, the lung(s) shall be allocated to the heart/lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with the UNOS Lung Allocation System, the heart shall be allocated to the heart/lung candidate from the same donor "after the heart has been offered to all heart and heart-lung potential transplant recipients in allocation classifications 1 through 4" Candidates with allocation classifications 1 through 4 falls within adult status 1 or 2 or pediatric status 1A.

Specific criteria for prioritizing donor thoracic organs for transplant are provided by the Organ Procurement and Transplantation Network (OPTN) and implemented through a contract with UNOS. Donor thoracic organs are prioritized by UNOS on the basis of recipient medical urgency,



distance from donor hospital, and pediatric status. Individuals who are most severely ill (status 1A) are given highest priority.

The following factors are considered in assessing the severity of cardiac illness: reliance on continuous mechanical ventilation, infusion of intravenous inotropes, and/or dependency on mechanical circulatory support (i.e., total artificial heart, intra-aortic balloon pump, extracorporeal membrane oxygenator, ventricular assist device). Factors considered in assessing the severity of pulmonary illness include increased pulmonary artery systolic pressure, pulmonary arterial hypertension, and/or elevated pulmonary vascular resistance.

Additional criteria may be considered in pediatric individuals, including diagnosis of an OPTNapproved congenital heart disease diagnosis, presence of ductal dependent pulmonary or systemic circulation, and diagnosis of hypertrophic or restrictive cardiomyopathy while less than one year old. Of note, pediatric heart transplant candidates who remain on the waiting list at the time of their 18<sup>th</sup> birthday without receiving a transplant continue to qualify for medical urgency status based on the pediatric criteria.

In both adult and pediatric individuals, isolated cardiac or pulmonary transplantations are preferred to combined heart/lung transplantation when medical or surgical management-other than organ transplantation-is available.

Full OPTN guidelines are available online (available at: https://optn.transplant.hrsa.gov/governance/policies/) Accessed September 11, 2024.

Individuals who are considered temporarily unsuitable to receive a thoracic organ transplant may be assigned an inactive status.

## Contraindications

The factors below are potential contraindications subject to the judgment of the transplant center:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage diseases not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence



- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

## **Benefit Application**

See individual's plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.

#### **Evidence Review**

### Description

Heart/lung transplantation involves a coordinated triple operative procedure consisting of procurement of a donor heart/lung block, excision of the heart and lungs of the recipient, and implantation of the heart and lungs into the recipient. Heart/lung transplantation refers to the transplantation of one or both lungs and heart from a single cadaver donor.

## Background

Solid organ transplantation offers a treatment option for individuals with different types of end stage organ failure that can be lifesaving or provide significant improvements to an individual's quality of life.<sup>1</sup> Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Most heart/lung transplant recipients have Eisenmenger syndrome (37%), followed by idiopathic pulmonary artery hypertension (28%) and cystic fibrosis (14%). Eisenmenger syndrome is a form of congenital heart disease in which systemic-to-pulmonary shunting leads to pulmonary



vascular resistance. It is possible that pulmonary hypertension could lead to a reversal of the intracardiac shunting and inadequate peripheral oxygenation or cyanosis.<sup>2</sup>

## Heart/Lung Transplant

Combined heart/lung transplantation is intended to prolong survival and improve function in individuals with end-stage cardiac and pulmonary diseases. Due to corrective surgical techniques and improved medical management of pulmonary hypertension, the total number of individuals with Eisenmenger syndrome has seen a decline in recent years. Additionally, heart/lung transplants have not increased appreciably, but for other indications, it has become more common to transplant a single or double lung and maximize medical therapy for heart failure, rather than perform a combined transplant. For those indications, individual survival rates following heart/lung transplantations are similar to lung transplant rates. Bronchiolitis obliterans syndrome is a major complication. One-, 5-, and 10-year individual survival rates for heart/lung transplants performed between 1982 and 2014 were estimated at 63%, 45%, and 32%, respectively.<sup>3</sup>

In 2023, 46,630 transplants were performed in the USUS procured from more than 16,000 deceased donors and 6,900 living donors.<sup>4</sup> Of these transplants, 54 individuals received heart/lung transplants in the US in 2023 (total 1,537 heart-lung transplants done to date in US). As of June 2024, 41 individuals were on the waiting list for heart/lung transplants.

## **Summary of Evidence**

For individuals who have end-stage cardiac and pulmonary disease who receive combined heart/lung transplant, the evidence includes a systematic review, case series, and registry data. The relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. The available literature reports on outcomes after heart/lung transplantation. Given the exceedingly poor expected survival rates without transplantation, this evidence is sufficient to demonstrate that heart/lung transplantation provides a survival benefit in appropriately selected individuals. A transplant may be the only option for some individuals with end-stage cardiopulmonary disease. Heart/lung transplant is contraindicated for individuals in whom the procedure is expected to be futile due to comorbid disease or for whom posttransplantation care is expected to worsen comorbid conditions significantly. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.



For individuals who have a combined heart/lung transplant complicated by graft failure or severe dysfunction of the heart/lung and who receive a combined heart/lung retransplant, the evidence includes case series and registry data. The relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. A very limited amount of data has suggested that, after controlling for confounding variables, survival rates after primary and repeat heart/lung transplants are similar. Findings are inconclusive due to the small number of cases of repeat heart/lung transplants reported in the published literature. Repeat heart/lung transplantation is, however, likely to improve outcomes in individuals with a prior failed transplant who meet the clinical criteria for heart/lung transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

## **Ongoing and Unpublished Clinical Trials**

A search of **ClinicalTrials.gov** in June 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

## **Practice Guidelines and Position Statements**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence. Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## International Society for Heart and Lung Transplantation

In 2021, the International Society for Heart and Lung Transplantation updated its consensusbased guidelines on the selection of lung transplant recipients.<sup>25</sup> These guidelines made the following statements about lung transplantation:

"Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:



- High (>50%) risk of death from lung disease within two years if lung transplantation is not performed.
- High (>80%) likelihood of five-year post-transplant survival from a general medical perspective provided that there is adequate graft function."

For combined heart/lung transplant, the guidelines state:

"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 guideline goes on to state: "The primary indication for heart-lung transplant is pulmonary hypertension, either secondary to idiopathic pulmonary arterial hypertension or congenital heart disease (CHD)."

The guidelines also mentioned: "...candidates free from complex CHD or left ventricular compromise can achieve comparable outcomes with isolated bilateral lung transplant. Similarly, patients with advanced lung disease and cardiac pathology amenable to surgical repair may be candidates for lung transplant concurrent with the appropriate corrective cardiac procedure."

## Medicare National Coverage

Heart/lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria.<sup>26</sup> The Centers for Medicare & Medicaid Services have stated that, under certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures safety and efficacy objectives.

## **Regulatory Status**

Solid organ transplants are a surgical procedure and, as such, is not subject to regulation by the US Food and Drug Administration (FDA).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

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#### History

Date	Comments
11/01/19	New policy, approved October 4, 2019. Content previously addressed in policy 7.03.509. Policy created with literature search through June 2019. Heart and lung transplants may be considered medically necessary when criteria are met. Policy statement on transplantation of HCV viremic organs is taken from BCBSA policy 7.03.14.
11/01/20	Annual Review, approved October 22, 2020. Policy updated with literature review through June 2020; references added. Policy statements unchanged.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through June 24, 2021; no references added. Policy statements unchanged.
11/01/22	Annual Review, approved October 10, 2022. Policy updated with literature review through June 10, 2022; reference added. Minor editorial refinements to policy



Date	Comments
	statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/23	Annual Review, approved October 9, 2023. Policy updated with literature review through June 13, 2023; no references added. Removed the policy statement regarding the transplantation of HCV-viremic solid organs to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational. Otherwise, policy statements unchanged.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 19, 2024; reference added. Policy statements unchanged.

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

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