MEDICAL POLICY – 7.03.08
Heart/Lung Transplant

BCBSA Ref. Policy: 7.03.08, 7.03.14
Effective Date: Nov. 1, 2019
Last Revised: Oct. 4, 2019
Replaces: Extracted from 7.03.509

RELATED MEDICAL POLICIES:
7.03.07 Lung and Lobar Lung Transplant
7.03.09 Heart Transplant

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Heart/lung transplant</td>
<td>Heart/lung transplantation is considered investigational in all other situations not outlined above.</td>
</tr>
<tr>
<td>HCV (hepatitis C) viremic</td>
<td>The transplantation of HCV-viremic solid organs (kidney, lung, heart, liver, small bowel, pancreas) to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational.</td>
</tr>
<tr>
<td>solid organs</td>
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</table>

**Documentation Requirements**

The patient’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 patient has end stage cardiac and pulmonary disease with the presence of one of the listed diagnoses
**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>CPT</strong></td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
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<tr>
<td><strong>HCPCS</strong></td>
<td>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</td>
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**Related Information**

**Definitions of Terms**

**Eisenmenger complex:** A congenital condition associated with ventricular septal defect (VSD) and pulmonary artery hypertension and eventually pulmonary vascular obstructive disease (PVOD) 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 “if no suitable Status 1A isolated heart candidates are eligible to receive the heart” (Organ Procurement and Transplantation Network [2018]).
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. Patients 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 (ie, 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 (>60 mm Hg), pulmonary arterial hypertension, and/or elevated pulmonary vascular resistance.

Additional criteria may be considered in pediatric patients, including diagnosis of an OPTN-approved congenital heart disease diagnosis, presence of ductal dependent pulmonary or systemic circulation, and diagnosis of hypertrophic or restrictive cardiomyopathy while less than 1-year-old. Of note, pediatric heart transplant candidates who remain on the waiting list at the time of their 18th birthday without receiving a transplant continue to qualify for medical urgency status based on the pediatric criteria.

In both adult and pediatric patients, 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 October 2019.

Status 7 patients are considered temporarily unsuitable to receive a thoracic organ transplant.

**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 member’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**

*Heart/Lung Candidates Requiring Transplantation*

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.¹
Treatment

Combined heart/lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiac and pulmonary diseases. Due to corrective surgical techniques and improved medical management of pulmonary hypertension, the total number of patients 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, patient survival rates following heart/lung transplantations are similar to lung transplant rates. Bronchiolitis obliterans syndrome is a major complication. One-, 5-, and 10-year patient survival rates for heart/lung transplants performed between 1982 and 2014 were estimated at 63%, 45%, and 32%, respectively.²

In 2017, 29 individuals received heart/lung transplants in the U. S. As of April 2018, 51 patients were on the waiting list for heart/lung transplants.³

Summary of Evidence

For individuals who have end-stage cardiac and pulmonary disease who receive combined heart/lung transplant, the evidence includes case series and registry data. The relevant outcomes are overall survival (OS), 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 patients. A transplant may be the only option for some patients with end-stage cardiopulmonary disease. Heart/lung transplant is contraindicated for patients 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 a meaningful 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 OS, 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 patients 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 a meaningful improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in June 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

**Practice Guidelines and Position Statements**

*International Society for Heart and Lung Transplantation*

The International Society for Heart and Lung Transplantation (2014) updated its consensus-based guidelines on the selection of lung transplant recipients. 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 2 years if lung transplantation is not performed.
- High (>80%) likelihood of surviving at least 90 days after lung transplantation.
- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function."

For combined heart/lung transplant, the guidelines have stated that patients with irreversible myocardial dysfunction or irreparable congenital defects in conjunction with intrinsic lung disease or severe pulmonary arterial hypertension are appropriate candidates for heart/lung transplantation. The guidelines also mentioned that isolated bilateral lung transplantation is associated with comparable or better outcomes in most patients with pulmonary hypertension associated with right ventricular failure.
The American Society of Transplantation

The American Society of Transplantation (2017) convened a consensus conference of experts to address issues related to the transplantation of hepatitis C virus (HCV) viremic solid organs into HCV non-viremic recipients and concluded that the transplantation of organs from HCV viremic donors into HCV-negative recipients should be conducted only under monitored IRB-approved protocols and studies.

Medicare National Coverage

Heart/lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare & Medicaid Services has 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

Heart/lung transplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration 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. Heart/lung transplants are included in these regulations.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/01/19</td>
<td>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.</td>
</tr>
</tbody>
</table>

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). ©2019 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
لا يمكن تقديم خدمات أو معلومات مطلوبة بشكل مجاني.

Mainland Chinese:
中华人民共和国公民在中华人民共和国境内申请或者接受预特拉加蓝保险提供的服务或接受服务过程中，如遇以下情况，可以申请相应的服务或帮助。

Kreyòl ayisyen (Creole):
Ovye sa a re teko boule sa a se dife akon la.

Italian (Italian): 
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動。保留您的健康保險或交費用補貼。您有權利免費以您的母語得到本文訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).
Este aviso contiene información importante. Es posible que contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog): Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakaop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang pital sa dito na sa paunawa na ito. Ang pinakamahalagang impormasyon ay maaaring naglalaman sa paunawa na ito. Ang mga impormasyon ay maaaring kumกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกกก://