

(70308)

<b>Medical Benefit</b>	<b>Effective Date:</b> 04/01/14	<b>Next Review Date:</b> 01/18
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 01/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17

***Preauthorization is required and must be obtained through Case Management.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>• With end-stage cardiac and pulmonary disease</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Combined heart/lung transplant</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Medical management</li> <li>• Single lung transplant</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Overall survival</li> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Treatment-related mortality</li> <li>• Treatment-related morbidity</li> </ul>

### 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.

### Summary of Evidence

The evidence for combined heart/lung transplant in patients who have end-stage cardiac and pulmonary disease includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. The available literature describes outcomes after heart/lung transplantation. Given the exceedingly poor expected survival without transplantation, this evidence is sufficient to demonstrate that heart/lung transplantation provides a survival benefit in appropriately selected patients. It may be the only option for some patients with end-stage cardiopulmonary disease. Heart/lung transplant is contraindicated in patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. Based on this evidence and established guidelines, heart/lung transplant may be considered likely to improve outcomes for those who meet clinical criteria and do not have contraindications to the procedure. A very limited amount of data suggest that, after controlling for confounding variables, survival rates after primary and repeat heart/lung transplants is similar. Findings are not conclusive due to the small number of cases of repeat heart/lung transplants reported in the published literature. Repeat heart/lung transplantation is likely to improve outcomes in patients with a failed prior transplant who meet the clinical criteria for heart/lung transplantation.

## Policy

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:

- irreversible primary pulmonary hypertension with heart failure;
- non-specific severe pulmonary fibrosis, with severe heart failure;
- Eisenmenger complex with irreversible pulmonary hypertension and heart failure;
- cystic fibrosis with severe heart failure;
- chronic obstructive pulmonary disease with heart failure;
- emphysema with severe heart failure;
- pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

Heart/lung retransplantation after a failed primary heart/lung transplant may be considered **medically necessary** in patients who meet criteria for heart/lung transplantation.

Heart/lung transplantation is considered **investigational** in all other situations.

## Policy Guidelines

Individual transplant facilities may have their own additional requirements or protocols that must be met in order for the patient to be eligible for a transplant at their facility.

Potential contraindications subject to the judgment of the transplant center:

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
3. Untreated systemic infection making immunosuppression unsafe, including chronic infection
4. Other irreversible end-stage disease not attributed to heart or lung disease
5. History of cancer with a moderate risk of recurrence
6. Systemic disease that could be exacerbated by immunosuppression
7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

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 UNOS Lung Allocation System (LAS), 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. Status 1A is described below (Organ Procurement and Transplantation Network, 2015).

### *Cardiac Specific-Criteria*

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 the United Network for Organ Sharing (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 IA) are given highest priority. Criteria from OPTN for listing status are as follows (Organ Procurement and Transplantation Network, 2015).

Adult Patients (18 years of age or older)

## STATUS 1A

A patient is admitted to the listing transplant center hospital and has at least one of the following devices or therapies in place:

1. Mechanical circulatory support that includes at least one of the following:
  - a) Total artificial heart
  - b) Intra-aortic balloon pump, or
  - c) Extracorporeal membrane oxygenator (ECMO)
2. Continuous mechanical ventilation
3. Requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of left ventricular filling pressures.

A patient has one of the following devices or therapies in place (with or without being admitted to the listing transplant center hospital):

1. Mechanical circulatory support that includes at least one of the following:
  - a) Left ventricular assist device (LVAD)
  - b) Right ventricular assist device (RVAD)
  - c) Left and right ventricular assist devices (BiVAD)
2. Mechanical circulatory support and there is medical evidence of significant device-related complications including, but not limited to, thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias.

## STATUS 1B

A patient has at least one of the following devices or therapies in place:

1. Left ventricular assist device (LVAD)
2. Right ventricular assist device (RVAD)
3. Left and right ventricular assist devices (BiVAD)
4. Continuous infusion of intravenous inotropes

A patient that does not meet Status 1A or 1B is listed as Status 2.

*Pediatric Patients*

A candidate listed as Status 1A meets at least one of the following criteria:

1. Requires assistance with a mechanical ventilator;
2. Requires assistance with a mechanical assist device (e.g., ECMO);
3. Requires assistance with a balloon pump;
4. Is younger than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

5. Requires infusion of a single high dose of an intravenous inotrope or multiple intravenous inotropes or multiple inotropes (e.g., addition of dopamine at greater than or equal to 5.0 µg/kg/min); or
6. Has a life expectancy without a heart transplant of less than 14 days.

A candidate listed as Status 1B meets at least one of the following criteria:

1. Requires infusion of low-dose single inotropes;
2. Is younger than six months old and does not meet the criteria for Status 1A; or
3. Is in the less than 5<sup>th</sup> percentile for the candidates expected height and/or weight according to most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart;
4. Is 1.5 or more standard deviations below the candidate's expected height growth or weight growth according to the most recent CDC National Center for Health Statistics pediatric clinical growth chart.

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

### Medicare Advantage

If a transplant is needed, we arrange to have the Medicare–approved transplant center review and decide whether the patient is an appropriate candidate for the transplant.

### Background

Combined heart/lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiac and pulmonary diseases. Most 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. Eventually, pulmonary hypertension may lead to a reversal of the intracardiac shunting and inadequate peripheral oxygenation, or cyanosis.<sup>1</sup>

However, the total number of patients with Eisenmenger syndrome has been declining in recent years, as a result of corrective surgical techniques and improved medical management of pulmonary hypertension. Heart/lung transplants have not increased appreciably for other indications either, as 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. In these, patient survival rates are similar to lung transplant rates. Bronchiolitis obliterans syndrome is a major complication; one-, five- and 10-year patient survival rates are 68%, 50%, and 40%, respectively.<sup>1</sup>

In 2014, 24 individuals received heart/lung transplants in the United States. As of the end of October 2015, there were 49 patients on the waiting list for heart/lung transplants.<sup>2</sup>

### 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.

## Related Protocols

Heart Transplant

Lung and Lobar Lung Transplant

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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