Heart/Lung Transplant

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.

FDA 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.

POLICY STATEMENT
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;
- nonspecific 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
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 disease not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence
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- Systemic disease that could be exacerbated by immunosuppression
- 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 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, 2017).

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 a 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 (at https://optn.transplant.hrsa.gov/governance/policies/).

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

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**RATIONALE**

**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. 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 rates without transplantation, this evidence is sufficient to demonstrate that heart/lung transplantation provides a survival benefit in appropriately selected patients. 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.
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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. 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 not conclusive 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
The International Society for Heart and Lung Transplantation issued consensus-based guidelines on the selection of lung transplant recipients in 1998, 2006,23 and most recently updated in 2014.24 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 guideline 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage

Heart/lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria.25 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.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


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**POLICY HISTORY**

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>March 2012</td>
<td>New Policy</td>
<td>Policy updated with literature search. No change to policy statement. Reference 6 added; other references renumbered or removed.</td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search. Policy statement on retransplantation added and 1 stated that all other indications are considered investigational. References 5, 12 and 13 added; other references renumbered or removed.</td>
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<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature search, adding reference 4. No changes to the policy statement were made.</td>
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<tr>
<td>March 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 6, 2015; references 6, 8, 14, and 18 added. Policy statements unchanged.</td>
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