The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required and must be obtained through Case Management. 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.

**Description**

The 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. A heart/lung transplantation refers to the transplantation of one or both lungs and heart from a single cadaver donor.

**Background**

Combined heart/lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiac and pulmonary diseases. The majority of 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. (1)

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; 1-, 5-, and 10-year patient survival rates are 68%, 50%, and 40%, respectively. (1)

In 2012, 29 individuals received heart/lung transplants in the United States. As of the end of September 2013, there were 48 patients on the waiting list for heart/lung transplants. (2)

**Related Protocols**

- Lung and Lobar Lung Transplant
- Heart Transplant

**Policy (Formerly Corporate Medical Guideline)**

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 transplantation 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 Guideline

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. (3)

Cardiac Specific

The United Network for Organ Sharing (UNOS) prioritizes donor thoracic organs according to the severity of illness as follows:

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:
(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
   1. Left and/or right ventricular assist device implanted
   2. Total artificial heart
   3. Intra-aortic balloon pump, or
   4. Extracorporeal membrane oxygenator (ECMO)
(b) Mechanical circulatory support
(c) Mechanical ventilation
(d) Continuous infusion of inotropes and continuous monitoring of left ventricular filling pressures
(e) If criteria a, b, c, or d are not met such status can be obtained by application to the applicable Regional Review Board.

**Status 1B**

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

1. left and/or right ventricular device implanted, or
2. continuous infusion of intravenous inotropes.

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

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

**Benefit Application**

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.

**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.

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.


