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## Subject: Heart and Lung Transplant

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### 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. A heart/lung transplantation refers to the transplantation of one or both lungs and heart from a single cadaver donor. Combined heart/lung transplantation is intended to prolong survival and improve function in those with end-stage cardiac and pulmonary diseases.

**Summary and Analysis of Evidence:** UpToDate review “Heart-lung transplantation in adults” (Singer, Mooney; 2024) states, “(p)atients with concomitant refractory end-stage heart disease and chronic end-stage lung disease should undergo evaluation to determine if they are candidates for heart-lung transplantation. The most common indication for heart-lung transplantation is complex congenital heart disease with Eisenmenger syndrome (systemic-to-pulmonary communication, pulmonary arterial disease causing severe pulmonary hypertension, and cyanosis). Heart-lung transplant is also infrequently indicated in patients with concomitant end-stage pulmonary disease (eg, idiopathic pulmonary arterial hypertension [IPAH] or cystic fibrosis) and either right ventricular failure with objective evidence of right ventricular fibrosis or infarction or refractory left ventricular failure. Where possible, isolated lung or heart transplantation is preferred to heart-lung transplantation because of several major disadvantages with the combined procedure. The need to procure a heart–lung block can lead to increased waiting time and increased mortality among patients awaiting combined heart-lung transplantation compared with those waiting for isolated heart or lung transplants. Other disadvantages include exposure of the recipient to risks of both graft coronary artery vasculopathy and chronic lung allograft dysfunction. In addition, heart-lung recipients may be disadvantaged by the obligate requirement for cardiopulmonary bypass during surgery and the physiological effects of a denervated heart.” Sertic et al (2020) compared outcomes of bilateral lung transplantation with cardiac defect repair to combined heart/lung transplantation in adult patients with Eisenmenger syndrome using the UNOS database of heart/lung

transplantations performed from 1987 to 2018. Among 442 patients who underwent thoracic transplantation, 316 patients underwent heart/lung transplantation and 126 patients underwent double-lung transplantation with concomitant cardiac defect repair. Overall survival was similar between patients who underwent double-lung transplantation and those who underwent heart/lung transplantation at 1 year (63.1% vs 68.0%, respectively), 5 years (38.5% vs 47.3%), and 10 years (30.2% vs 30.5%) posttransplant. Yusen et al (2016) reported on the survival of adult heart/lung transplant recipients using the ISHLT database. Among the 3775 primary heart/lung transplants performed between 1982 and 2014, the 3-month, 1-year, 3-year, 5-year, and 10-year survival rates were 71%, 63%, 52%, 45%, and 32%, respectively. The overall median survival during this period (1982 to 2014) was 3.4 years. Those who survived to 1 year had a conditional median survival of 10.3 years. Survival improved over time, with a median survival of 2.1 years for patients who received the transplant between 1982 and 1993, 3.9 years for patients between 1994 and 2003, and 5.8 years for patients between 2004 and 2014. Heart/lung transplant recipients in the 2004 to 2014 group had a median conditional survival beyond 10 years. Compared with lung-only transplantation (median conditional survival, 8.0 years), heart/lung transplant recipients had better long-term survival (median conditional survival, 10.3 years). Hill et al (2015) compared survival following heart/lung transplantation with double-lung transplantation for idiopathic pulmonary arterial hypertension among adult transplant recipients in the Scientific Registry of Transplant Recipients database between 1987 and 2012. Among the 928 idiopathic pulmonary arterial hypertension patients, 667 underwent double-lung transplantation, and 261 underwent heart/lung transplantation. Overall, the adjusted survival was similar between double-lung transplantation and heart/lung transplant recipients. However, for recipients hospitalized in the intensive care unit, double-lung transplantation was associated with worse outcomes than heart/lung transplantation recipients. Jayarajan et al (2014) compared the mortality rates (at 1 month and 5 years posttransplant) of heart/lung transplant recipients who required pretransplant ventilation or extracorporeal membrane oxygenation (ECMO) with controls. Median survival times were 10 days, 181 days, and 1547 days among patients with pretransplant ECMO, patients with a mechanical ventilator, and the control group, respectively. Patients with pretransplant ECMO had poorer survival than the control group at 30 days (20.0% vs 83.5%) and 5 years (20.0% vs 47.4%). Similarly, patients requiring ventilation prior to transplantation had worse survival at 1 month (77.3% vs 83.5%) and 5 years (26.5% vs 47.4%) compared with the control group. The use of ECMO or mechanical ventilation as a bridge to transplantation was independently associated with mortality on multivariate analysis. Riggs et al (2020) assessed outcomes for pediatric heart/lung transplantation among children with CHD with Eisenmenger syndrome, CHD without Eisenmenger syndrome, primary pulmonary hypertension, and "other" categories using the UNOS database of heart/lung transplantations performed from 1987 to 2018. Among 209 heart/lung transplantations performed during the specified time frame, 17.7% had CHD with Eisenmenger syndrome, 19.1% had CHD without Eisenmenger syndrome, 33.5% had primary pulmonary hypertension, 2.9% were retransplants, and 26.8% had another diagnosis. One-year, 5-year, and 10-year survival rates post-transplant, respectively, were 75%, 44%, and 32% for pediatric patients with CHD with Eisenmenger syndrome, 56%, 21%, and 16% for patients with CHD without Eisenmenger syndrome, 77%, 41%, and 33% for patients with primary pulmonary hypertension, 40%, 0%, and 0% for retransplanted patients, and 70%, 44%, and 20% for patients with other diagnoses. Compared to the reference group of pediatric patients with primary pulmonary hypertension, patients with CHD without Eisenmenger syndrome and patients who were retransplanted had significantly lower survival rates. Goldfarb et al (2016) reported on the survival of pediatric lung and heart/lung transplant recipients

using the ISHLT database. Among the 698 pediatric heart/lung transplant recipients, median survival was 3.0 years, and conditional median survival was 7.8 years. There was no statistically significant difference in survival by indication, recipient age group, or time period of transplant for pediatric heart/lung transplant recipients. Yusen et al (2014) reported on outcomes for adult heart/lung transplants, with a focus on retransplantation, using data from the ISHLT Registry. From 1982 to 2012, 90 adults had a first heart/lung retransplant after a previous heart/lung transplant. These 90 patients had a median survival of 0.3 years, with unadjusted survival rates of 52%, 43%, 36%, and 27% at 3 months, 1 year, 3 years, and 5 years, respectively. Those who survived to 1 year had a conditional median survival of 7.9 years. A study by Shuhaiber et al (2008) reviewed data from the UNOS registry. They identified 799 primary heart/lung transplants and 19 repeat heart/lung transplants. Using Kaplan-Meier survival analysis, the observed median survival times were 2.08 years after the primary transplant and 0.34 years after repeat transplant. In addition, reviewers analyzed survival data in matched pairs of primary and repeat transplant patients who were matched on a number of potentially confounding demographic and clinical characteristics. Matches were not available for 4 repeat transplant patients. For the 15 repeat transplant patients with primary transplant matches, survival time did not differ significantly between groups. Being on a ventilator was statistically significantly associated with decreased survival time. Yoosabai et al (2015) conducted a retrospective review of 23,171 heart transplant recipients in the OPTN/UNOS database to identify whether pretransplant malignancy increased the risk of posttransplant malignancy. Posttransplant malignancy was diagnosed in 11.5% of recipients during the study period. A history of any pretransplant malignancy was associated with an increased risk of overall posttransplant malignancy, including skin and solid organ malignancies. Koval et al (2019) conducted a retrospective study to assess outcomes among 29 HIV-infected patients who underwent thoracic transplant at 14 sites in the U.S. and Europe. Of the 29 patients, 21 received heart transplants, 7 received lung transplants, and 1 received a heart/lung transplant. At the time of transplantation, 2 patients had detectable HIV RNA levels and the remainder were undetectable. All patients were on a 3-drug antiretroviral regimen at the time of transplantation. One year survival did not differ for patients with HIV who received heart (90%) and lung (86%) transplants compared to control patients without HIV from the ISHLT database. Three and 5-year survival rates among patients with HIV were 73% and 64%, respectively, for heart transplants and 80% and 75%, respectively, for lung transplants. Acute cellular rejection occurred in 14 heart transplant patients and 2 lung transplant patients. Infections were reported in 8 heart transplant patients and 7 lung transplant patients. Six patients (5 heart transplant and 1 lung transplant) developed malignancy; none were AIDS-defining malignancies. Suppression of HIV RNA continued for at least 1 year for all patients. One patient who had a detectable viral load at the time of (heart) transplant died after 3 years from AIDS-related complications and graft failure. However, this was due to lack of adherence and lack of appropriate follow-up. The second patient with a detectable viral load at the time of transplant lived for 10 years post-transplant. There are few data directly comparing outcomes for patients with and without HIV or for combined heart/lung transplants.

## **POSITION STATEMENT:**

### **Certificate of Medical Necessity**

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

Heart/lung transplantation **meets the definition of medical necessity** for carefully selected individuals with end-stage cardiac and pulmonary disease including, but not limited to, one of the following conditions:

- 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 **meets the definition of medical necessity** in individuals who meet criteria for heart/lung transplantation.

Heart/lung transplantation is considered **experimental or investigational** in all other situations, as available clinical evidence does not support safety and effectiveness.

Potential contraindications to heart/lung transplant (subject to the judgment of the transplant center) include:

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

## BILLING/CODING INFORMATION:

### CPT Coding:

33930	Donor cardiectomy-pneumonectomy, (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation.
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy

## REIMBURSEMENT INFORMATION:

None applicable.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage:** The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Heart Transplants (260.9), located at [cms.gov](https://www.cms.gov).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

## DEFINITIONS:

No guideline specific definitions apply.

## RELATED GUIDELINES:

[Lung and Lobar Lung Transplant, 02-30000-10](#)

[Heart Transplant, 02-33000-23](#)

[Ventricular Assist Devices and Total Artificial Hearts, 02-33000-25](#)

## OTHER:

**Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)**

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

**Florida Statute 627.64197 Coverage for organ transplants.**—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 627.65736 Coverage for organ transplants.**—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 641.31075 Coverage for organ transplants.**—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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organ transplants; and 641.31075 – Coverage for organ transplants. Accessed at <http://www.flSenate.gov/>.

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

## GUIDELINE UPDATE INFORMATION:

01/01/01	Medical Coverage Guideline developed.
12/15/02	Reviewed and revised; statement was added regarding transplant facilities.
11/15/04	Scheduled review; statement added regarding organ transplantation in HIV-positive recipients.
01/01/05	Annual HCPCS coding update: added code 33933, revised code descriptor for 33930.
06/15/05	Revision of guideline, consisting of removal of investigational statement regarding HIV-positive recipients.
06/15/06	Scheduled review; no change in coverage statement.
06/15/07	Scheduled review (consensus); no change in coverage statement; reformatted guideline; updated references.
07/15/08	Scheduled review; no change in position statement.
01/01/09	Annual HCPCS coding update: updated descriptor for code 33960.
07/15/09	Scheduled review; no change in position statement. Update references.
10/15/10	Revision; related ICD-10 codes added.
01/01/12	Annual HCPCS coding update. Added 33961. Revised 33960 descriptor.
06/15/12	Revision; added Medicare Advantage program exception for extracorporeal photopheresis (ECP) following lung allograft transplantation. Updated references.
06/15/14	Scheduled review. Revised description, position statement and program exceptions section. Updated references.
01/01/15	Annual CPT/HCPCS update. Deleted 33960, 33961.

12/15/19	Scheduled review. Revised description. Maintained position statement and updated references.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical gifts and coverage of organ transplants. Updated references.
09/15/21	Scheduled review. Maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
08/15/23	Scheduled review. Revised description. Maintained position statement and updated references.
07/15/24	Scheduled review. Revised description. Maintained position statement and updated references.