

Manual: IU Health Plans

Department: Utilization Management

Policy # MP089

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X Medicare Advantage X Commercial

Transplant: Heart-Lung Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for concurrent transplantation of heart and lung.

II. Scope

This policy applies to all IU Health Plans and Utilization Management staff having decision-making responsibilities where authorization is required for Fully insured and Medicare Advantage (MA) plans.

III. Exceptions

IU Health Plans does not consider **any of the following** to be medically necessary and is therefore **not covered**:

- 1. Transplant will not be covered for members who have other serious medical problems or are not psychologically willing to undergo the stressful surgery and post-operative care as needed
- 2. Heart Xeno-transplantation for any cardiac condition is considered experimental and not covered.

IV. Definitions

Heart Lung (cardiopulmonary) Transplantation is the simultaneous surgical replacement of the heart and lungs in a patient with end stage cardiac and pulmonary disease.

V. Policy Statements

- A. IU Health Plans considers Heart-Lung transplant medically necessary when the member meets **one or more of the following** criteria:
 - 1. Must meet all of the following criteria:
 - a. The member has no medical, cognitive, substance abuse, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens
 - b. No systemic illnesses limiting life expectancy to less than 2 years (i.e. malignancy, autoimmune disease, Duchenne muscular dystrophy)
 - c. The member meets the institution's selection criteria for heart-lung transplantation.
 - d. The member must first undergo stringent physical and psychological evaluation to determine eligibility for transplant.
 - e. All other medical and surgical therapies that might be expected to yield both short- and long-term survival comparable to that of transplantation must have been tried or considered.

- f. Heart-lung transplantation may be medically necessary for members with irreversible, progressively disabling, end-stage cardiopulmonary disease including any **ONE of the following** conditions listed below:
 - 1. Refractory NYHA Class III or IV heart failure associated with one of the following:
 - a. End-stage chronic obstructive pulmonary disease
 - b. Severe pulmonary fibrosis
 - c. Cystic Fibrosis
 - d. Severe primary pulmonary hypertension
 - 2. Irreversible, uncontrollable pulmonary hypertension associated with **ONE of the following**:
 - a. Refractory NYHA Class III or IV heart failure
 - b. Pulmonary fibrosis
 - c. Cardiomyopathy and/or severe coronary heart disease
 - d. Congenital heart disease with complications that cannot be repaired with conventional surgical approaches to the heart and lungs
 - 3. Eisenmenger's complex with irreversible pulmonary hypertension and refractory NYHA Class III or IV heart failure
 - 4.End-stage lung disease with malignant ventricular arrhythmias that is uncontrollable despite optimal pharmacologic or electrophysiologic treatments (including implantable cardioverter-defibrillator)
 - 5. Subsequent operation for failure of original graft
- g. Heart-lung transplantation in HIV+ members is considered medically necessary when **ONE** or **MORE** of the following conditions are met:
 - 1. Must meet all of the following:
 - a. The member has a life expectancy of at least five years
 - b. CD4 count ≥200 cells/mL for at least six months
 - c. Undetectable HIV viremia (<50 copies/mL) for six months
 - d. Demonstrated adherence to highly active antiretroviral therapy (HAART) regiment for ≥ six months
 - e. Available antiretroviral treatment options post-transplant
 - 2. Does not apply to this member

CODES

CPT CODES	Description
33927	Removes heart and implants artificial heart as a temporary measure until donor heart found or for patients not eligible for a heart transplant who require permanent mechanical cardiac support
33928	Remove and replace artificial heart due to failure or improved mechanical heart
33929	Removal of mechanical heart in preparation for donor heart
33930	Removes donor heart and lungs
33933	Backbench preparation for cadaver donor heart/lung
33935	Heart-lung transplant with recipient cardiotomy- pneumonectomy
33940	Surgical removal of heart for transplantation and placed in cold preservation solution
33944	Donor heart preparation from cold solution for transplantation
33945	Transplants donor heart into recipient

VI. Procedures

None

VII. Rationale

Heart/lung transplantation is considered a standard treatment for individuals who meet the specific medical necessity criteria outlined in this document. Combined heart-lung transplants are reserved for those where a heart or lung transplant alone would not sufficiently address their condition and improve their chances of survival.

In 2021, the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation updated its guidelines for selecting heart-lung transplant candidates. The updated criteria state that candidates must meet the requirements for lung transplant listing and have significant dysfunction of one or more additional organs or meet criteria for a non-pulmonary organ transplant while also having significant pulmonary dysfunction. The primary reason for heart-lung transplantation is pulmonary hypertension, either due to idiopathic pulmonary arterial hypertension or congenital heart disease (CHD). Previous guidelines included conditions like NYHA class IV symptoms despite optimal medical management, a cardiac index below 2 l/min/m2, and a mean right atrial pressure above 15 mmHg; however, the decision to list a patient for heart-lung transplant remains complex.

Heart-lung and other multi-organ transplants should only be performed at centers with experience in such procedures and with specialists available for managing each transplanted organ. The American Heart Association/American College of Cardiology's 2018 guidelines for adults with congenital heart disease (CHD) recommend heart-lung transplantation for conditions like Eisenmenger syndrome that cause irreversible pulmonary hypertension (Stout, 2019).

Valapour and colleagues (2021) reported that lung transplants declined in 2020, coinciding with the COVID-19 pandemic. However, the number of candidates on the waiting list increased, and mortality on the list grew, although the time to transplant improved, with 38% of candidates waiting fewer than 90 days. One-year post-transplant survival was 85.3%, with 67% surviving to three years and 54.3% surviving to five years.

As of September 2022, UNOS reported 31 active candidates on the heart-lung transplant list, with 45 transplants performed in 2021, including 2 in children. Survival rates for transplants performed between 2008-2015 were 81% at one year, 58.3% at three years, and 50.2% at five years.

The 2021 changes to the lung allocation system, including the introduction of a Lung Composite Allocation Score (CAS) for candidates aged 12 and older, aimed to better predict survival and improve fairness in lung transplant allocation. The new methodology includes factors like medical urgency, survival likelihood, matching challenges, age, and prior living organ donations.

In 2023, the OPTN expanded eligibility for pediatric heart status 1A and 1B candidates under age 2 to accept blood type-incompatible donors.

Heart transplantation for cardiomyopathy caused by amyloidosis has gained attention. This condition leads to restrictive cardiomyopathy, progressive heart failure, and death, and transplant outcomes are often worse due to its systemic nature. However, light chain suppressive therapies for amyloidosis have shown to improve transplant outcomes. A 2020 study by Barrett and colleagues of 31 individuals with cardiac amyloidosis found that post-transplant outcomes were similar between those with amyloid and those without. Despite complications like infection, organ rejection, and renal dysfunction, survival rates did not

differ significantly between the two groups. Larger studies are needed to confirm these findings, as the study was limited in size and scope.

The ACC's 2023 consensus supports heart transplant as an option for select patients with advanced heart failure from ATTR-CM and AL-CM. For these patients, the allocation system prioritizes heart transplants as Status 4 due to the lack of effective long-term support options. The ACC emphasizes that multiple factors, including clinical history, physical exams, and tests, should be considered when identifying candidates for heart transplant or advanced heart failure therapies.

VIII. References/Citations

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IX. Appendices

None

X. Responsibility

Medical Director

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