

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>HEART/LUNG TRANSPLANT</b>
<b>POLICY NUMBER</b>	<b>MP 9.014</b>

<b>CLINICAL BENEFIT</b>	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
<b>Effective Date:</b>	<b>3/1/2024</b>

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### I. 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 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 may be considered **medically necessary** in patients who meet criteria for heart/lung transplantation.

Heart/lung transplantation is considered **investigational** in all other situations, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

#### Policy Guidelines

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 "after the heart has been offered to all heart and heart-lung potential transplant recipients in allocation classifications 1 through 4". Candidates with allocation classifications 1 through 4 falls within adult status 1 or 2 or pediatric status 1A.

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 (e.g., 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, 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 combine 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/>).

Patients who are considered temporarily unsuitable to receive a thoracic organ transplant may be assigned an inactive status.

***Cross-references:***

- MP 1.026** Total Artificial Hearts and Implantable Ventricular Assist
- MP 9.007** Heart Transplant
- MP 9.015** Lung and Lobar Lung Transplant

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**II. PRODUCT VARIATIONS**

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

**III. DESCRIPTION/BACKGROUND**

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Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient’s quality of life. Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Most heart/lung transplant 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. It is possible that pulmonary hypertension could lead to a reversal of the intracardiac shunting and inadequate peripheral oxygenation or cyanosis.

Combined heart/lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiac and pulmonary diseases. Heart-lung transplantation (HLTx) is currently the best treatment for patients who have end-stage heart and lung failure. Due to corrective surgical techniques and improved medical management of pulmonary hypertension, the total number of patients with Eisenmenger syndrome has seen a decline in recent years. Additionally, heart/lung transplants have not increased appreciably, but for other indications, 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. For those indications, patient survival rates following heart/lung transplantations are similar to lung transplant rates. Bronchiolitis obliterans syndrome is a major complication. One-, 5-, and 10-year patient survival rates for heart/lung transplants performed between 1982 and 2014 were estimated at 63%, 45%, and 32%, respectively.

In 202, 42,889 transplants were performed in the United States procured from 36,421 deceased donors and 6,469 living donors. Of these 42,889 transplants, fifty-one individuals received

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heart/lung transplants in the US in 2021 (total 1432 heart-lung transplants done to date in US). As of June 2023, 36 patients were on the waiting list for heart/lung transplants

**REGULATORY STATUS**

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

**IV. RATIONALE**

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**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 reports on 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 post transplantation 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.

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 inconclusive 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.

**V. DEFINITIONS**

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**BLUE DISTINCTION CENTERS FOR TRANSPLANT (BDCT)** is a cooperative effort of the Blue Cross and Blue Shield Plans, the Blue Cross and Blue Shield Association and participating medical institutions to provide patients who need transplants with access to leading centers through a coordinated, streamlined program of transplant management.

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**END-STAGE** refers to the final phase of a disease process

**NEW YORK HEART ASSOCIATION (NYHA) FUNCTIONAL CLASS** is used to assess the functional class of patients with heart failure

**CLASS I** – No limitation during ordinary activity

**CLASS II** – Slight limitation by shortness of breath and/or fatigue during moderate exertion or stress

**CLASS III** – Symptoms with minimal exertion that interfere with normal daily activity

**CLASS IV** – Inability to carry out any physical activity

### VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

### VII. DISCLAIMER

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*Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Covered when medically necessary:**

Procedure Codes						
S2055	S2060	S2061	S2152	33930	33933	33935
33940	33944	33945				

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<b>ICD-10-CM Diagnosis Code</b>	<b>Description</b>
E84.0	Cystic fibrosis with pulmonary manifestations
E84.8	Cystic fibrosis with other manifestations
I27.0	Primary pulmonary hypertension
I27.1	Kyphoscoliosis heart disease
I27.21	Secondary pulmonary arterial hypertension
I27.22	Pulmonary hypertension due to left heart disease
I27.23	Pulmonary hypertension due to lung diseases and hypoxia
I27.24	Chronic thromboembolic pulmonary hypertension
I27.29	Other secondary pulmonary hypertension
I27.83	Eisenmenger's syndrome
I27.81	Cor pulmonale (chronic)
I27.89	Other specified pulmonary heart diseases
I27.9	Pulmonary heart disease, unspecified
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure"
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure

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<b>ICD-10-CM Diagnosis Code</b>	<b>Description</b>
I50.89	Other heart failure
I50.9	Heart failure, unspecified
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.89	Other specified chronic obstructive pulmonary disease
J44.9	Chronic obstructive pulmonary disease, unspecified
J84.10	Pulmonary fibrosis, unspecified
T86.32	Heart-Lung transplant failure

**IX. REFERENCES**

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**X. POLICY HISTORY**

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<b>MP 9.014</b>	<b>CAC 10/28/03</b>
	<b>CAC 6/28/05</b>
	<b>CAC 2/28/06</b>
	<b>CAC 2/27/07</b>
	<b>CAC 1/29/08</b>
	<b>CAC 1/27/09 Consensus review</b>
	<b>CAC 1/26/10 Consensus review</b>
	<b>CAC 9/15/10 Adopt BCBSA guidelines.</b>
	<b>CAC 10/25/11 Revised Description/Background including addition of absolute and relative contraindications from BCBSA policy update.</b>

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	<p><b>CAC 10/30/12 Consensus review.</b> References updated; Severe heart failure added to second bullet point of medically necessary statement. Contraindications moved to Policy Guidelines. Absolute and relative contraindications combined, and wording changed to be consistent with other solid organ transplant policies. FEP variation added.</p>
	<p><b>03/07/13</b> Codes reviewed</p>
	<p><b>CAC 1/28/14 Minor review.</b> Added medically necessary statement for retransplantation. References updated. Rationale section added.</p>
	<p><b>CAC 1/27/15 Consensus review,</b> no change to policy statements. References and rationale updated. Consensus reviewed added ICD 9 range and ICD 10 ranges. Updated codes.</p>
	<p><b>01/2015 Admin update.</b> New 2015 codes added to policy</p>
	<p><b>CAC 1/26/16 Consensus review.</b> No change to policy statements. References and rationale updated. Coding Reviewed.</p>
	<p><b>Admin update 1/1/17:</b> Product variation section reformatted.</p>
	<p><b>CAC 5/23/17 Consensus review.</b> No change to policy statements. References and rationale reviewed. Coding Reviewed.</p>
	<p><b>Admin update 10/1/17:</b> Added new ICD 10 codes effective from 10/1/17, deleted old ICD 10 codes and revised code description to the policy.</p>
	<p><b>1/1/18 Admin Update:</b> Medicare variations removed from Commercial Policies.</p>
	<p><b>2/9/18 Consensus review.</b> No change to policy statements. References and rationale updated. Coding Reviewed</p>
	<p><b>2/20/19 Consensus review.</b> No change to policy statements. References updated. Rational condensed.</p>
	<p><b>03/24/2020 Minor review.</b> Added investigational statement and literature. Revised Description/Background and FEP variation sections.</p>
	<p><b>5/19/2021 Consensus review.</b> No change to policy statement. Background, References and Rationale updated.</p>
	<p><b>10/12/2022 Consensus review.</b> No change to policy statement. Update to background, definitions, and ref.</p>
	<p><b>8/30/2023 Administrative review.</b> ICD-10-CM code: J4489 added as part of new code update. Effective date 10/1/2023.</p>
	<p><b>9/6/2023 Consensus review.</b> No change to policy statement. Background updated. References reviewed and updates. No change to coding.</p>
	<p><b>1/19/2024 Administrative update.</b> Clinical benefit added.</p>

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