

## Corporate Medical Policy

### Heart-Lung Transplantation

**File Name:** heart\_lung\_transplantation  
**Origination:** 5/1985  
**Last Review:** 3/2024

#### Description of Procedure or Service

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Combined heart/lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiac and pulmonary diseases. 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 2022, 42,889 transplants were performed in the United States procured from 36,421 deceased donors and 6468 living donors.<sup>4</sup> Of these 42,889 transplants, 51 individuals received heart/lung transplants in the US in 2022 (total 1486 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.

#### Related Policies:

Lung and Lobar Lung Transplantation

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

#### Policy

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**BCBSNC may provide coverage for a heart/lung transplant when the medical criteria and guidelines shown below are met.**

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## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Coverage is not provided for organs sold rather than donated to the recipient

## **When Heart-Lung Transplantation is covered**

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Human heart/lung transplantation is considered medically necessary for carefully selected patients with end-stage cardiac and pulmonary disease including, but not limited to, one of the following diagnoses:

1. Irreversible idiopathic arterial pulmonary hypertension with heart failure;
2. Non-specific severe pulmonary fibrosis, with severe heart failure;
3. Eisenmenger complex with irreversible pulmonary hypertension and heart failure;
4. Cystic fibrosis with severe heart failure;
5. Chronic obstructive pulmonary disease with heart failure;
6. Emphysema with severe heart failure;
7. Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

Heart/lung re-transplantation after a failed primary heart/lung transplant may be considered medically necessary in patients who meet criteria for heart/lung transplantation.

## **When Heart-Lung Transplantation is not covered**

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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

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## Policy Guidelines

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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. A 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 an 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 an improvement in the net health outcome.

Only those patients accepted for transplantation by a transplantation center and actively listed for transplant should be considered for prior review. Guidelines should be followed for transplant network or consortiums, if applicable.

Currently, Organ Procurement and Transplantation policy permits HIV-positive transplant candidates.

The British HIV Association and the British Transplantation Society 2017 updated guidelines on kidney transplantation in patients with HIV disease. These criteria may be extrapolated to other organs as follows:

- Adherent with treatment, particularly antiretroviral therapy
- Cluster of differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- No opportunistic infections for at least 6 months
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 33930, 33933, 33935, S2152*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual

Recommendations of the Consensus Conference on Candidate Selection for Heart Transplantation 1993, Miller et al. 1995 J Heart Lung Transplant 14:562-571. Relative contraindications include serum creatinine >3 or creatinine clearance under 25 cc/min; and age over 65.

See Selection and Treatment of Candidates for Heart Transplantation, approved by the American Heart Association Science Advisory and Coordinating Committee on July 24, 1995, published in Circulation 1995; 92:3593-3612.

Specialty Matched Consultant Advisory Panel 11/1999

Medical Policy Advisory Group 12/2/1999

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Specialty Matched Consultant Advisory Panel - 11/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 4/25/06

United Network for Organ Sharing (UNOS). Policy 3.7. Organ Distribution: Allocation of Thoracic Organs. UNOS Policies and Bylaws. United Network for Organ Sharing, Alexandria, VA. Revised 6/23/09. Retrieved 8/21/09 from [http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy\\_9.pdf](http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy_9.pdf)

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Medical Director review 1/2012

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The International Society for Heart and Lung Transplantation (ISHLT). Registries. Retrieved from <http://www.ishlt.org/registries/heartLungRegistry.asp>

Organ Procurement and Transplantation Network (OPTN). Retrieved from <http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>.

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<http://icvts.oxfordjournals.org/content/early/2013/04/10/icvts.ivt111.full.pdf+html?sid=80ca76a1-794b-4d33-bdb9-b48d0a93a262>

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Shuhaiber JH, Kim JB, Hur K, Gibbons RD, Nemeh HW, Schwartz JP, Bakhos M: Comparison of survival in primary and repeat heart transplantation from 1987 through 2004 in the United States. *Ann Thorac Surg* 2007, 83:2135-2141. [http://www.annalsthoracicsurgery.org/article/S0003-4975\(07\)00361-X/fulltext](http://www.annalsthoracicsurgery.org/article/S0003-4975(07)00361-X/fulltext)

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/14/13

Specialty Matched Consultant Advisory Panel review 6/2014

Medical Director review 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/13/14

Specialty Matched Consultant Advisory Panel review 6/2015

Medical Director review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/12/15

Specialty Matched Consultant Advisory Panel review 6/2016

Medical Director review 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/2015

Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 9/2017

Medical Director review, 9/2017

Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

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Medical Director review, 8/2018

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Medical Director review 6/2019

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Medical Director review 6/2020

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Working Party of the British Transplantation Society. Kidney and Pancreas Transplantation in Patients with HIV. Second Edition (Revised). British Transplantation Society Guidelines. Macclesfield, UK: British Transplantation Society; Published 2015. Updated 2017. [https://bts.org.uk/wp-content/uploads/2017/04/02\\_BTS\\_Kidney\\_Pancreas\\_HIV.pdf](https://bts.org.uk/wp-content/uploads/2017/04/02_BTS_Kidney_Pancreas_HIV.pdf).

Specialty Matched Consultant Advisory Panel review 3/2024

Medical Director review 3/2024

## Policy Implementation/Update Information

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5/85 Original Policy

8/88 Reviewed: Investigational

8/90 Evaluated: Eligible for coverage

Local Review Dates:

1/93 Reviewed: PCP Physician Advisory Group

11/94 Reviewed: PCP Physician Advisory Group

11/95 Reviewed: PCP Physician Advisory Group

6/96 Evaluated: Policy confirmed. Added specific diagnoses considered for possible coverage and contraindications.

8/97 Reaffirmed

## Heart-Lung Transplantation

- 9/99 Reviewed, reformatted, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 3/01 System changes.
- 12/01 Specialty Matched Consultant Advisory Panel review. No change to criteria. Coding format change.
- 11/03 Biannual review. Specialty Matched Consultant Advisory Panel review. Definition given to morbid obesity. Policy reformatted for consistency.
- 4/04 Code S2152 added to Billing/Coding section of policy.
- 1/6/05 Code 33933 added to Billing/Coding section of policy.
- 1/20/05 Format changes.
- 11/17/05 Biennial review. Specialty Matched Consultant Advisory Panel review 11/07/05. No change in policy.
- 11/19/07 Deleted age limitation from the When it is Not Covered section. Specialty Matched Consultant Advisory Panel review meeting 10/29/07. No change in policy statement. (adn)
- 12/7/09 Specialty Matched Consultant Advisory Panel review 10/30/09. No change in policy statement. (adn)
- 8/3/2010 Specialty Matched Consultant Advisory Panel review 6/2010. Removed Medical Policy number. References updated. (mco)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. Policy Guidelines updated. The section “When Heart-Lung Transplant is not Covered” has been updated with the following contraindications: “Absolute contra-indications for heart/lung transplants include, but are not limited to, the following conditions: Known current malignancy, including metastatic cancer; Recent malignancy with high risk of recurrence; Untreated systemic infection making immunosuppression unsafe, including chronic infection; or Other irreversible end-stage disease not attributed to heart or lung disease. Relative contraindications for heart/lung transplants include, but are not limited to, the following conditions: History of cancer with a moderate risk of recurrence; Systemic disease that could be exacerbated by immunosuppression; or Psychosocial or dependence conditions affecting ability to adhere to therapy” History of non-compliance, BMI, HIV positivity and lack of documentation of non-smoking status removed from contraindications. References updated. (mco)
- 2/7/12 Revised “When not Covered” section. Absolute and Relative contraindications have been combined and revised to “Potential contraindications subject to the judgment of the transplant center.” References updated. Medical Director review. (mco)
- 7/10/12 Specialty Matched Consultant Advisory Panel review 6/2012. No changes to Policy Statements or clinical criteria. (mco)
- 1/29/13 References updated. Description section updated. No changes to Policy Statements. (mco)

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- 7/16/13 Specialty Matched Consultant Advisory Panel review 6/2013. Medical Director review 6/2013. References updated. (mco)
- 1/14/14 Added the following statement to the “When Covered” section: “Heart/lung re-transplantation after a failed primary heart/lung transplant may be considered medically necessary in patients who meet criteria for heart/lung transplantation.” Description section updated. Policy Guidelines updated. References updated. (mco)
- 7/15/14 Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review 6/2014. No changes to Policy Statements. (mco)
- 2/10/15 Reference added. Description section updated to include updated information for transplants and waiting list volumes. No change to Policy Statements. (td)
- 9/1/15 Specialty Matched Consultant Advisory Panel review 6/2015. Medical Director review 6/2015. Policy Statements unchanged. (td)
- 4/1/16 Description section updated. Policy Guidelines updated. References updated. (td)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/2016. Medical Director review 6/2016. (jd)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/2017. (jd)
- 10/13/17 Minor update to Description section. Extensive revision to Policy Guidelines; no change to policy intent. References update. Medical Director review 9/2017. (jd)
- 7/27/18 Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)
- 9/28/18 Description section, policy guidelines and reference section updated. No change to policy intent. Medical Director review 8/2018. (jd)
- 7/1/19 Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)
- 6/30/20 References updated. Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)
- 7/1/21 Minor revisions to description section. Item #1 revised under When Covered section with current terminology as follows: replaced the term “primary” with “idiopathic pulmonary arterial hypertension.” References updated. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)
- 7/12/22 Minor updates only. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)
- 3/31/23 Minor updates to description. Related policies added. References added. Specialty Matched Consultant Advisory Panel review 3/2023. Medical Director review 3/2023. (tt)
- 4/1/24 Description, Regulatory Status, and Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 3/2024. Medical Director review 3/2024. (tt)



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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.