

Corporate Medical Policy

Heart-Lung Transplantation

File Name: heart_lung_transplantation
Origination: 5/1985
Last CAP Review: 6/2020
Next CAP Review: 6/2021
Last Review: 6/2020

Description of Procedure or Service

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.

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 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 1982-2014 were estimated at 63%, 45%, and 32%, respectively.

In 2017, 29 individuals received heart/lung transplants in the United States. As of April 2018, there were 51 patients on the waiting list for heart/lung transplants.

The U.S. Food and Drug Administration 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. Heart/Lung transplants are included in these regulations.

******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

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

Benefits Application

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

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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

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 primary 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

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

Policy Guidelines

The evidence for combined heart/lung transplant in patients who have end-stage cardiac and pulmonary disease includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. The available literature describes outcomes after heart/lung transplantation. Given the exceedingly poor expected survival

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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 co-morbid disease or in whom post-transplantation care is expected to significantly worsen co-morbid conditions significantly. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

The evidence 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, 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 not 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.

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

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. 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.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual

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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

Specialty Matched Consultant Advisory Panel - 12/2001

BCBSA Medical Policy Reference Manual - 4:2002, 7.03.08

Specialty Matched Consultant Advisory Panel - 11/2003

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 7/9/09

Specialty Matched Consultant Advisory Panel 6/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/11/10

Specialty Matched Consultant Advisory Panel review 6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/10/11

Medical Director review 1/2012

Specialty Matched Consultant Advisory Panel review 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 11/8/12

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>.

Olland A, Falcoz PE, Canuet M, Massard G. Should we perform bilateral-lung or heart-lung transplantation for patients with pulmonary hypertension? Interact Cardiovasc Thorac Surg. 2013 Apr 10. Retrieved from <http://icvts.oxfordjournals.org/content/early/2013/04/10/icvts.ivt111.full.pdf+html?sid=80ca76a1-794b-4d33-bdb9-b48d0a93a262>

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Specialty Matched Consultant Advisory Panel review 6/2013

Medical Director review 6/2013

Shuhaiber JH, Kim JB, Hur K, Gibbons RD, Nemei 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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 8/2018

Medical Director review, 8/2018

Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.08, 9/2019

Specialty Matched Consultant Advisory Panel review 6/2020

Medical Director review 6/2020

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Policy Implementation/Update Information

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
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

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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)
- 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)

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6/30/20 References updated. Specialty Matched Consultant Advisory Panel review 6/2020.
Medical Director review 6/2020. (jd)

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.