Medical Coverage Policy

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Heart, Lung, and Heart-Lung Transplantation

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Overview

This Coverage Policy addresses transplantation of the thoracic organs (i.e., heart, lung), surgical procedures in which one or both of the diseased organs are replaced with the viable heart, lung(s), lung lobes, or combined heart and lung of an appropriate donor.

Cigna Omnibus Reimbursement Policy R24 addresses donor organ procurement and transport.

Coverage Policy

Heart transplantation in an adult is considered medically necessary for the treatment of ANY of the following:

- malignant ventricular arrhythmias unresponsive to medical and/or surgical therapy
- refractory angina that is not amenable or correctable by alternative medical or surgical therapies and leaves the individual in a New York Heart Association functional class III or IV
- end-stage heart failure with **EITHER** of the following:
  - disease that is not amenable or correctable by alternative medical therapies or leaves the individual in New York Heart Association functional class III or IV
  - disease that requires continuous intravenous inotropic or mechanical circulatory support

Heart transplantation in a child is considered medically necessary for the treatment of EITHER of the following:

- intractable heart failure
- congenital abnormality not amenable to surgical correction

Lung transplantation is considered medically necessary when BOTH of the following criteria are met:

- end-stage disease of lung parenchyma, airway and pulmonary vasculature that is not amenable to maximum alternative medical or surgical therapies
- severe, progressive symptoms despite optimal medical management, resulting in an unacceptable quality of life

Heart-lung transplantation is considered medically necessary when BOTH of the following criteria are met:

- end-stage cardiopulmonary disease where the replacement of either organ alone is unlikely to improve survival or quality of life
- the individual remains at a New York Heart Association functional class III or IV despite maximal medical and surgical management

Note: Selected candidates may be eligible for multi-organ transplantation. For each organ, the candidate should meet all of the criteria for selection for the individual transplant being considered. For a heart-kidney transplant, please refer to Coverage Policy 0146 Kidney Transplantation for the kidney transplant criteria.

Lung transplantation is considered not medically necessary for EITHER of following:

- coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function
- chest wall/spinal deformity that would pose a contraindication to transplantation

Heart, lung, or heart-lung transplantation is considered not medically necessary in an individual with ANY of the following contraindications to transplant surgery:

- malignancy that is expected to significantly limit future survival
- persistent, recurrent or unsuccessfully treated major or systemic infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
- a pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless ALL of the following are noted:
    - CD4 count greater than 200 cells/mm^3
    - HIV-1 ribonucleic acid (RNA) undetectable
    - stable anti-retroviral therapy for more than three months
    - absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections; or Kaposi's sarcoma or other neoplasm)

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

The OPTN's Equity in Access to Transplant page for heart transplant notes that overall disparities in access to deceased donor heart transplant among candidates on the waiting list have remained relatively stable over the last decade. The most noteworthy risk-adjusted differences in access to heart transplants correspond to four key factors: Blood Type; Donation Service Area, or DSA; Height; and Weight. Differences associated with other factors beyond these four are relatively small, with factor-specific standard deviations approaching zero.

The OPTN's Equity in Access to Transplant page for lung transplant notes that though the overall disparity metric for access to deceased donor lung transplants among candidates on the waiting list has fluctuated over the past decade, the overall level of disparity in 2019 remains about the same as it was in 2010. The most noteworthy risk-adjusted differences in access to lung

transplants correspond to four key factors: Blood Type; Donation service area, or DSA; Height; and Age. Differences associated with other factors beyond these four are relatively small, with factor-specific standard deviations approaching zero. The transplant rate advantage experienced by pediatric candidates is "discounted" from the factor-specific standard deviation estimate for age.

General Background

Heart Transplantation

A heart transplant replaces an individual's failing heart with a donor heart. The failing heart may be a result of heart failure, coronary heart disease, irregular heartbeat or some other severe heart condition. In individuals with congenital heart disease, the surgeon might also transplant the lungs with the heart.

The Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) 2022 Annual Data Report states that the number of heart transplants in the United States has continued to increase. Since 2011, pediatric heart transplants have increased 31.7% to 494 and adult heart transplants have increased 85.8% to 3,668 in 2022.
Since 2011, post-transplant mortality has been stable to slightly better; among recipients who underwent transplant in 2015-2017, the 1-, 3-, and 5-year pediatric survival rates were 93.7%, 89.2%, and 85.0%, respectively, and the adult survival rates were 91.3%, 85.7%, and 80.4% (Colvin et al., 2024).

Indications for Heart Transplantation

ADULT
The 2023 OPTN adult heart allocation criteria for medical urgency status states that the candidate must be at least 18 years old at the time of registration with the following requirements (OPTN, May 2024):

Adult Heart Status 1 requires that the patient has at least one of the following conditions:
- is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO)
- is supported by non-dischargeable, surgically implanted, non-endovascular biventricular support device
- is supported by mechanical circulatory support device (MCSD) with life-threatening ventricular arrhythmia

Adult Heart Status 2 requires that the patient has at least one of the following conditions:
- is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)
- is supported by a total artificial heart (TAH), biventricular assist device (BiVAD), right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients
- is supported by a MCSD device that is malfunctioning
- is supported by a percutaneous endovascular mechanical circulatory support device
- is supported by an intra-aortic balloon pump (IABP)
- is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation

Adult Heart Status 3 requires that the patient has at least one of the following conditions:
- is supported by a dischargeable left ventricular assist device and is exercising 30 days of discretionary time

- is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring
- is supported by VA ECMO after 7 days; percutaneous endovascular circulatory support device or IABP after 14 days
- is supported by non-dischargeable, surgically implanted, non-endovascular LVAD after 14 days
- is supported by an MCSD with one of the following:
    - hemolysis
    - pump thrombosis
    - device infection
    - mucosal bleeding
    - aortic insufficiency
    - right heart failure

Adult Heart Status 4 requires that the patient has at least one of the following conditions:

- is supported by dischargeable LVAD without discretionary 30 days
- is supported by inotropes without hemodynamic monitoring
- is a re-transplant
- has a diagnosis of one of the following:
    - congenital heart disease (CHD)
    - ischemic heart disease with intractable angina
    - hypertrophic cardiomyopathy
    - restrictive cardiomyopathy
    - amyloidosis

Adult Heart Status 5 is for patients who are on the waitlist for at least one other organ at the same hospital and status 6 is for all remaining active candidates.

PEDIATRIC

Heart candidates less than 18 years old at the time of registration may be assigned any of the following:

- Pediatric status 1A
- Pediatric status 1B
- Pediatric status 2
- Inactive status

Pediatric Heart Status 1A includes patients less than 18 years old at the time of registration with at least one of the following conditions:

- requires continuous mechanical ventilation or assistance of an intra-aortic balloon pump and is admitted to the hospital that registered the patient
- has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion and is admitted to the hospital that registered the patient
- has a hemodynamically significant congenital heart disease diagnosis, requires infusion of multiple intravenous inotropes or a high dose of a single intravenous inotrope and is admitted to the hospital that registered the patient
- requires assistance of a mechanical circulatory support device

Pediatric Heart Status 1B includes at least one of the following criteria:

- requires infusion of one or more inotropic agents but does not qualify for pediatric status 1A
- younger than one year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy.

Pediatric Heart Status 2 Requirements: If the candidate is less than 18 years old at the time of registration and does not meet the criteria for pediatric status 1A or 1B but is suitable for transplant, then the candidate may be assigned pediatric status 2. A candidate's pediatric status 2 does not require any recertification (OPTN, May 2024).

The International Society for Heart and Lung Transplantation (ISHLT) 2016 Listing Criteria for Heart Transplantation (Mehra, et al., 2016) recommendations and noted Contraindications include but are not limited to:

Class I*
- Diagnostic right heart catheterization should be performed on all adult candidates in preparation for listing for cardiac transplantation and periodically until transplantation

Class IIa
- It is reasonable to recommend weight loss to achieve a BMI of ≤35 kg/m2 before listing for cardiac transplantation.
- Diabetes with end-organ damage (other than non-proliferative retinopathy) or persistent poor glycemic control (glycosylated hemoglobin [HbA1c] >7.5% or 58 mmol/mol), despite optimal effort, is a relative contraindication for transplant.
- It is reasonable to consider the presence of irreversible renal dysfunction (eGFR <30 ml/min/1.73 m^2) as a relative contraindication for HT alone.

Class IIb
- Heart failure survival prognosis scores may be assessed along with the cardiopulmonary exercise testing to determine prognosis and guide listing for transplantation for ambulatory patients.
- Clinically severe symptomatic cerebrovascular disease (CVD) may be considered a contraindication to transplantation. Peripheral vascular disease (PVD) maybe considered a relative contraindication for transplantation when its presence limits rehabilitation and revascularization is not a viable option
- Carefully selected patients >70 years of age may be considered for cardiac transplantation
- Assessment of frailty (3 of 5 possible symptoms, including unintentional weight loss of ≥10 pounds within the past year, muscle loss, fatigue, slow walking speed, and low levels of physical activity) could be considered when assessing candidacy

Class III
- Listing patients solely on the criteria of heart failure survival prognostic scores should not be performed (ISHLT/Mehra, et al., 2016).

The International Society for Heart and Lung Transplantation (ISHLT) 2023 Guidelines for Mechanical Circulatory Support (Saeed, et al., 2023) states the two major indications for durable mechanical circulatory support (DMCS) include bridge to cardiac transplantation (BTT) or permanent therapy for end-stage refractory heart failure, referred to as destination therapy (DT). Indications for mechanical circulatory support include:

*Class I
- Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for durable mechanical circulatory (DMCS) support for short term support as bridge to transplantation or bridge to candidacy.
- Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for DMCS for long-term support if

transplant is unlikely to occur in the short-term, if a period of support will improve transplant candidacy, or as destination therapy for patients who are ineligible for transplant.

Class IIa

- Patients with dilated cardiomyopathy, particularly of recent onset and nonischemic etiology refractory to maximal medical therapy, should be considered for DMCS as bridge-to-recovery. Pharmacological treatment should be with maximally tolerated neurohormonal modulation, and surveillance for recovery of left ventricular function should be undertaken (ISHLT/Saeed, et al., 2023).

*Class I: Strongly supported by evidence or consensus opinion. Such a treatment is strongly recommended
Class IIa: Evidence or consensus opinion mostly in favor. Such a treatment is reasonable to consider.
Class IIb: Evidence or consensus opinion conflicting or less well established. Such a treatment may be reasonable to consider.
Class III: Evidence or consensus opinion is against as the treatment is not effective or harmful. Such a treatment should be avoided.

The American College of Cardiology/American Heart Association (ACC/AHA) Guideline for the Management of Hypertrophic Cardiomyopathy (2024) lists some recommendations that address heart transplantation:

- In patients with nonobstructive hypertrophic cardiomyopathy (HCM) and advanced HF (NYHA functional class III to class IV), cardio-pulmonary exercise stress testing should be performed to quantify the degree of functional limitation and aid in selection of patients for heart transplantation or mechanical circulatory support (COR I*).
- In patients with nonobstructive HCM and advanced HF (NYHA functional class III to class IV despite guideline-directed management and therapy [GDMT]), cardiopulmonary exercise test (CPET) should be performed to quantify the degree of functional limitation and aid in selection of patients for heart transplantation or mechanical circulatory support (COR I).
- In patients with nonobstructive HCM and advanced HF (NYHA functional class III to class IV despite GDMT) or with life-threatening ventricular arrhythmias refractory to maximal GDMT, assessment for heart transplantation in accordance with current listing criteria is recommended (COR I).
- In patients with nonobstructive HCM and advanced HF (NYHA functional class III to class IV despite GDMT) who are candidates for heart transplantation, continuous-flow LVAD therapy is reasonable as a bridge to heart transplantation (COR IIa).
- In patients with HCM and recurrent, poorly tolerated life-threatening ventricular tachyarrhythmias refractory to maximal antiarrhythmic drug therapy and ablation, heart transplantation assessment is indicated in accordance with current listing criteria (COR I).

*Class of Recommendation (COR)
Class I: is recommended
Class IIa: is reasonable
Class IIb: may be reasonable
Class III: is not recommended (Writing Committee Members/ACC, 2024).

The 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis notes:

- 7.6.2. Indications for heart transplantation

In select patients with amyloid transthyretin cardiomyopathy (ATTR-CM) and amyloid monoclonal immunoglobulin light chain cardiomyopathy (AL-CM) with advanced/stage D HF, heart transplantation may be an option, and the current adult donor allocation system provides priority as Status 4 to amyloid CM, given the lack of durable mechanical circulatory support (MCS) support options.

- 7.6.3. Contraindications to heart transplantation
  As multiorgan amyloid infiltration is common, the contraindications to heart transplantation in patients with cardiac amyloidosis center around the degree of extracardiac involvement and the impact of this involvement on post-transplant morbidity and mortality (Writing Committee/ACC, 2023).

The 2022 ACC/AHA/HFSA guideline for the management of heart failure (Heidenreich, et al., 2022) noted that heart transplantation is the established treatment for eligible patients with stage D heart failure that is refractory to guideline-directed medical therapy (GDMT), device, and surgical management. Heart transplantation provides a mortality and morbidity benefit to selected patients with stage D HF.

The 2018 ACC/AHA guideline for the management of adults with congenital heart disease (ACHD) stated that cardiac transplantation is reasonable in adults with Fontan palliation with signs and symptoms of protein-losing enteropathy. Additionally, in patients with ACHD and Eisenmenger syndrome exhibiting deteriorating functional ability, mechanical circulatory and pulmonary support, lung transplantation with concomitant repair of anatomic cardiovascular defects, and heart–lung transplantation have been applied (Stout, et al., 2019).

The 2016 AHA scientific statement on chronic heart failure in congenital heart disease stated that transplantation is a reasonable consideration in pediatric patients with heart failure associated with systemic ventricular dysfunction with previously repaired or palliated chronic heart disease (CHD) when it is associated with significant growth failure attributable to the heart disease and CHD with severe limitation of exercise and activity. Additional indications included: CHD with normal ventricular function if the following anatomic and physiological conditions are present and not amenable to surgical intervention (Stout, et al., 2016):

- proximal coronary arteries have severe stenosis or atresia
- atrioventricular or systemic semilunar valve(s) with moderate to severe stenosis or insufficiency
- symptomatic arterial oxygen desaturation (cyanosis)
- persistent protein-losing enteropathy despite optimal medical-surgical therapy

Lung Transplantation

Lung transplantation is the surgical replacement of the lung(s) of an individual with end-stage pulmonary disease. The type of lung transplantation procedure used (i.e., lobar, single, or double) and donor type (i.e., deceased or living) are based upon the candidate's condition and indication for transplantation, and the availability of donor organs. For most recipients, lung transplantation is a palliative, rather than curative treatment, the primary goal being the projected survival benefit. It is an accepted treatment of last resort for persons with end-stage lung disease who do not respond to alternative medical or surgical treatment. Improvements in quality of life, in addition to survival, should be used to assess the effectiveness of the procedure.

The OPTN/SRTR 2022 Annual Data Report states in the year 2022, there were 2,743 lung transplants performed in the United States, representing an increase of 174 lung transplants from 2,569 in 2021.Lung allocation policy changes were implemented on September 30, 2021, to prepare for the eventual implementation of the Composite Allocation Score system, which

occurred on March 9, 2023. The changes on September 30, 2021, affected the Lung Allocation Score (LAS) calculation and reflected an updated candidate and recipient cohort to improve the predictions of the waitlist and posttransplant mortality models used to calculate the LAS. The LAS in use in 2022 continued to use a 2:1 ratio of 1-year waitlist and 1-year post-transplant survival estimates. For adult transplants performed in 2021, 1-year post-transplant mortality was 12.2%, and for transplants performed in 2017, 5-year posttransplant mortality was 40.4%. Across all pediatric recipients who underwent lung transplant in 2015-2017, 1-, 3-, and 5-year patient survival were 84.4%, 64.8%, and 56.3%, respectively (Valapour, et al., 2024).

Indications for Lung Transplantation

According to the OPTN Administrative Rules and Definitions policy (May 2024), the lung composite allocation score is the combined total of the candidate's lung medical urgency score, lung post-transplant outcomes score, lung biological disadvantages score, lung patient access score and lung placement efficiency score. The lung composite allocation score is awarded on a scale from 0 to 100. Candidates will be rank-ordered by lung composite allocation score. If two or more candidates have the same lung composite allocation score, the tied candidates will be ranked by order of their registration date (oldest to newest).

Each candidate is assigned a diagnosis group, based on their lung disease diagnosis, which is used in the calculation of their medical urgency score and their post-transplant survival score.

Group A
A candidate is in Group A if the candidate has any of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia
- Sarcoidosis with either Pulmonary artery (PA) mean pressure of 30 mm Hg or less, or PA mean pressure missing
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B
A candidate is in Group B if the candidate has any of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)
- Portopulmonary hypertension

- Pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C
A candidate is in Group C if the candidate has any of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D
A candidate is in Group D if the candidate has any of the following diagnoses:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Combined pulmonary fibrosis and emphysema (CPFE)
- Constrictive bronchiolitis
- COVID-19: acute respiratory distress syndrome
- COVID-19: pulmonary fibrosis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia,
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman’s disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)

- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Scleroderma – restrictive
- Silicosis
- Sjogren's syndrome
- Surfactant protein B deficiency
- Surfactant protein C deficiency
- Teratoma
- Wegener's granuloma – restrictive (OPTN, May 2024).

The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates (Leard, et al., 2021) indicated that:

ADULT
Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:

- high (> 50%) risk of death from lung disease within 2 years if lung transplantation is not performed
- high (> 80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function

PEDIATRIC
In addition to general recommendations for adults, considerations for referring children for lung transplant evaluation include the following:

- Patients with cystic fibrosis < 18 years of age should be referred when:
  - FEV1 is < 50% predicted with markers of increased disease severity
  - FEV1 is < 50% predicted with rapidly declining FEV1
  - FEV1 is <40% predicted
- Patients with PAH < 18 years of age should be referred when despite optimal PAH therapy:
  - EPPVDN intermediate or high-risk category
  - Need for IV or SC prostacyclin therapy
  - Significant RV dysfunction
  - WHO functional class > III
  - Elevated or rising BNP or NTproBNP
  - Diminished growth
  - Progressive disease despite appropriate therapy or recent hospitalization for worsening of PAH
  - Signs of secondary liver or kidney dysfunction due to PAH
  - Potentially life-threatening complications such as recurrent hemoptysis or syncope
  - Being considered for atrial septostomy or reverse Potts shunt as a palliative procedure (footnote: transplantation may be an option post procedure)
- Patients with alveolar capillary dysplasia, pulmonary vein stenosis refractory to intervention, and pulmonary venoocclusive disease should be referred for urgent evaluation and listing.

In addition to general recommendations for adults, considerations for listing children for lung transplant include the following:

- Patients with CF < 18 years of age should be listed when FEV1 < 30% predicted
- Patients with PAH <18 years of age should be listed when they are in the EPPVDN high risk category and on optimal therapy without improvement

LUNG RE-TRANSPLANTATION

- The timing of re-transplant is a complex issue and requires consideration of the rate of deterioration, time since initial transplant, the need for supportive therapies and donor lung availability, which may be limiting in some cases.
- Survival after re-transplant is inferior to that seen with the primary operation and should only be undertaken in carefully selected candidates.
- In the evaluation of patients being considered for lung re-transplant, particular emphasis should be focused on understanding the possible reasons for the graft failure, such as alloimmunization, poor adherence, gastroesophageal reflux, or repeated infections.

MULTI-ORGAN TRANSPLANTATION

- Heart-lung and other multi-organ transplantation should be limited to centers with experience in such procedures and where specialists are available to manage each of the transplanted organs.
- Candidates should meet the criteria for lung transplant listing and have significant dysfunction of one or more additional organs or meet the listing criteria for a non-pulmonary organ transplant and have significant pulmonary dysfunction.
- Waiting times are likely to be longer and the likelihood of receiving a transplant is reduced when an individual requires more than one organ. Thus, referral should occur earlier in the disease course if multi-organ transplantation may be considered.

DISEASE SPECIFIC CANDIDATE RECOMMENDATIONS

Additionally, there are disease specific considerations for which transplantation may be indicated. These include:

Chronic Obstructive Airway Disease:

- BODE index (i.e., body mass index [B], degree of obstruction [O], dyspnea [D], exercise capacity [E]), score of 7-10
- FEV1 (i.e., forced expiratory volume in the first second) < 20% predicted
- history of severe exacerbations
- moderate to severe pulmonary hypertension
- chronic hypercapnia

Interstitial Lung Disease (ILD):

- a 10% or greater decrease in FVC (i.e., forced vital capacity) or FVC > 5% with radiographic progression during six months of follow-up
- a decline in diffusion capacity of carbon monoxide (DLCO) > 10% during 6 months of follow-up
- decrease in pulse oximetry <88% during a six-minute walk test
- confirmed pulmonary hypertension
- hospitalization for decline in respiratory status, pneumothorax or acute exacerbation

Cystic Fibrosis:

- FEV1 < 25% predicted
- chronic respiratory failure with hypoxemia or hypercapnia
- any exacerbation requiring mechanical ventilation
- nutritional status declining particularly with BMI < 18 kg/m^2
- pulmonary hypertension
- frequent hospitalization
- rapid decline in lung function or progressive symptoms
- recurrent massive hemoptysis despite bronchial artery embolization
- World Health Organization Functional Class IV

Non-CF Bronchiectasis:

- For individuals with non-CF bronchiectasis, similar criteria as with CF for referral and listing for lung transplantation is reasonable, though providers should recognize that prognosis is highly variable with many patients experiencing a more stable course.

Pulmonary Arterial Hypertension (PAH):
- European Society of Cardiology (ESC)/European Respiratory Society (ERS) high risk or REVEAL risk score > 10 on appropriate PAH therapy, including IV or SC prostacyclin analogues
- Progressive hypoxemia
- Progressive liver or kidney dysfunction due to PAH (not end-stage)
- Life-threatening hemoptysis

Lymphangioleiomyomatosis (LAM):
- despite mammalian target of rapamycin (mTOR) inhibitor therapy there is:
  - disease progression
  - severely abnormal lung function (e.g. FEV1 < 30% predicted)
  - NYHA class III or IV exertional dyspnea
  - hypoxemia at rest
  - pulmonary hyptertension
  - pneumothorax refractory to treatment

Thoracic Malignancy:
- Lung transplant should be limited to very select cases of lung-limited adenocarcinoma in situ, minimally invasive adenocarcinoma, or lepidic predominant adenocarcinoma for patients in whom:
  - surgical resection is not feasible either because of multifocal disease or significant underlying pulmonary disease;
  - multifocal disease has resulted in significant lung restriction and respiratory compromise;
  - medical oncology therapies have failed or are contraindicated; and
  - lung transplant is expected to be curative.

Acute Respiratory Distress Syndrome (ARDS):
- continuous requirement for mechanical ventilator support and/or extracorporeal life support (ECLS)
- no expectation of clinical recovery
- irreversible lung damage

ABSOLUTE CONTRAINDICATIONS
Candidates with these conditions are considered too high risk to achieve successful outcomes post lung transplantation. Factor or condition that significantly increases the risk of an adverse outcome post-transplant and /or would make transplant most likely harmful for a recipient. Most lung transplant programs should not transplant patients with these risk factors except under very exceptional or extenuating circumstances:
- Lack of patient willingness or acceptance of transplant
- Malignancy with high risk of recurrence or death related to cancer
- Glomerular filtration rate < 40 mL/min/1.73m2 unless being considered for multi-organ transplant
- Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia)
- Stroke within 30 days
- Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant

- Acute liver failure
- Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery
- Septic shock
- Active extrapulmonary or disseminated infection
- Active tuberculosis infection
- HIV infection with detectable viral load
- Limited functional status (e.g. non-ambulatory) with poor potential for post-transplant rehabilitation
- Progressive cognitive impairment
- Repeated episodes of non-adherence without evidence of improvement (Note: For pediatric patients this is not an absolute contraindication and ongoing assessment of non-adherence should occur as they progress through different developmental stages.)
- Active substance use or dependence including current tobacco use, vaping, marijuana smoking, or IV drug use
- Other severe uncontrolled medical condition expected to limit survival after transplant

(ISHLT / Leard, et al., 2021).

Heart-Lung Transplantation

Heart-lung transplantation is the procedure of choice for selected patients with concomitant end-stage heart failure and end-stage lung disease. Combined heart and lung transplantation is limited to patients in whom it offers the only surgical option for their end-stage cardiac and pulmonary disease. The procedure of choice for pulmonary parenchymal and vascular diseases in the absence of left heart dysfunction is single or double lung transplantation.

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.

Indications — Adult patients 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 adult 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 (UpToDate/Singer, et al., 2024).

The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates (Leard, et al., 2021) indicated that:

- Heart-lung and other multi-organ transplantation should be limited to centers with experience in such procedures and where specialists are available to manage each of the transplanted organs.
- Candidates should meet the criteria for lung transplant listing and have significant dysfunction of one or more additional organs or meet the listing criteria for a non-pulmonary organ transplant and have significant pulmonary dysfunction.

- Waiting times are likely to be longer and the likelihood of receiving a transplant is reduced when an individual requires more than one organ. Thus, referral should occur earlier in the disease course if multi-organ transplantation may be considered (ISHLT/Leard, et al., 2021).

The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation (Chambers, et al., 2019) reported number of adult heart-lung transplants remains static with 59 procedures reported in 2017. There were no significant changes in indication for heart-lung transplantation, with pulmonary hypertension accounting for the majority of procedures. The trend for a small but increasing number of heart-lung transplants performed for idiopathic interstitial pneumonia (IIP) and other diagnoses continued unabated in the past year. This increased activity has occurred at the expense of heart-lung transplantation for CF, which has become a rare indication compared with the 1990s. As has been the case for the past few years, an increasing proportion of heart-lung transplant recipients are older than 50 years at the time of transplant. The trend for older, non-CF recipients is particularly strong in North America, where 34% of recipients are now 50 years or older, and 8% 60 years or older.

Renal dysfunction, diabetes mellitus, malignancy, and chronic allograft rejection (allograft vasculopathy and BOS) are unfortunately common complications of heart-lung transplantation. The median survival for heart-lung transplant recipients has increased over the past few decades to 6.5 years in the most recent era; much of this mortality occurs early after transplantation, with median survival, conditional on survival to 1 year after transplant, almost double that at 12.8 years. Recipients transplanted for IIP have particularly poor outcomes, with median survival of only 1.9 years, significantly lower than median survival for CF recipients (ISHLT/Chambers, et al., 2019).

The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation (Hayes, et al., 2019) reported pediatric heart-lung transplantation is a rare procedure for children with cardiopulmonary failure, with most transplantations performed in the 11- to 17-year age group. From January 2010 to June 2018, significant differences were seen with respect to indication for pediatric heart-lung transplantation between Europe, North America, and other Regions. In Europe, CF is a more common indication, whereas idiopathic pulmonary arterial hypertension (IPAH) and pulmonary hypertension (PH)-not IPAH are more common in North America and other Regions. Survival in pediatric heart-lung recipients across the 3 major indications (CF, IPAH, and PH-not IPAH) was not statistically different (ISHLT/Hayes, et al., 2019).

Re-transplantation

Re-transplantation remains a controversial procedure, in part due to ethical concerns over the limited supply of organs. The recipient of the re-transplantation procedure often suffers from the systemic sequelae of short-or long-term immunosuppression, infection, and technical issues attributable to the initial transplantation surgery.

The International Society for Heart and Lung Transplantation (ISHLT) 2016 Listing Criteria for Heart Transplantation (Mehra, et al., 2016) notes that heart retransplantation remains a small portion of overall adult transplants performed, accounting for approximately 3% of all transplants. Although outcomes have improved in recent eras, retransplantation remains in the highest 1-year mortality group and is also a significant predictor of long-term mortality. More striking is the finding that the mortality for retransplantation in registry data is 18% at 30 days and 22% at 90 days. Even in pediatric patients, retransplantation confers a worse long-term mortality compared with that of primary HTs (63%, 46%, and 26% vs 72%, 60%, and 42% for 5, 10, and 20 years, respectively; $p<0.001$)

- Retransplantation is indicated for those patients who develop significant CAV with refractory cardiac allograft dysfunction, without evidence of ongoing acute rejection (ISHLT/Mehra, et al., 2016).

The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates (Leard, et al., 2021) notes that approximately 5% of all lung transplants performed are re-transplants. The outcomes after re-transplants are inferior compared to first lung transplants, particularly if the re-transplant is done within the first year after the original transplant or for patients with restrictive allograft syndrome (RAS).

- The timing of re-transplant is a complex issue and requires consideration of the rate of deterioration, time since initial transplant, the need for supportive therapies and donor lung availability, which may be limiting in some cases.
- Survival after re-transplant is inferior to that seen with the primary operation and should only be undertaken in carefully selected candidates.
- In the evaluation of patients being considered for lung re-transplant, particular emphasis should be focused on understanding the possible reasons for the graft failure, such as alloimmunization, poor adherence, gastroesophageal reflux, or repeated infections (ISHLT /Leard, et al., 2021).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Heart Transplants (260.9)	5/1/2008
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral

CPT®* Codes	Description
32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral
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
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

HCPCS Codes	Description
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

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Revision Details

Type of Revision	Summary of Changes	Date
Focused review	• Revised policy statement on lung transplantation.	12/15/2024
Annual review	• No clinical policy statement changes.	9/15/2024
Annual review	• Updated to new template and formatting standards.	9/15/2023