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.

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 from a deceased donor 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 0355 Liver and Liver-Kidney Transplantation for the kidney transplant criteria.

Lung transplantation is considered experimental, investigational or unproven 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)

General Background

Heart Transplantation
Heart transplantation is the therapy of choice in adults with end-stage heart failure, refractory angina, and malignant ventricular arrhythmias, who have received maximal medical treatment, are unlikely to survive the next 6–12 months and for whom there is no other surgical option (Mancini, 2022; Canter, et al., 2007; Butler, et al., 2004). According to the Organ Procurement and Transplantation Network (OPTN) Administrative Rules and Definitions policy, each heart transplant candidate is assigned a status that reflects the candidate's medical urgency for transplant (OPTN, July 2023).

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

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 with device malfunction/mechanical failure
- 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.

Justification for 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

Requirements for 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

The OPTN's national data for primary heart transplantation performed between 2008-2015 states that one-, three-, and five-year patient overall survival (OS) rates for primary transplantation were 90.9%, 85.6% and 78.6% respectively (based on OPTN data as of July 14, 2023).

The greatest risk factors for one-year mortality after heart transplantation include the need for end-organ support with extracorporeal membrane oxygenation and mechanical ventilation.

Furthermore, patients who undergo transplantation for congenital heart disease, restrictive cardiomyopathy, valvular cardiomyopathy, ischemic cardiomyopathy, hypertrophic cardiomyopathy and those undergoing retransplantation have lower one-year survival rates. Additional risk factors include younger and older recipient age, reduced estimated glomerular filtration rates, elevated total bilirubin levels, elevated pulmonary vascular resistance, and elevated panel of reactive antibodies at the time of transplant. Lastly, the severity of illness prior to transplantation is typically a predictor of adverse outcomes (Pham, 2022; Mahle, 2008; Canter, et al., 2007).

Indications for Heart Transplantation: An individual with refractory angina or end-stage intractable heart failure that is not amenable or correctable by alternative medical or surgical therapies and who has a New York heart Association (NYHA) III or IV functional class may be an appropriate candidate for heart transplantation. The New York Heart Association (NYHA) Functional Classification of Patients with Heart Disease is a subjective measure of functional capacity which describes the amount of activity an individual can do before the onset of heart failure symptoms is noted. Heart transplantation may also be indicated for an individual with malignant ventricular arrhythmias which are unresponsive to medical or surgical therapies.

In an infant or child, heart transplantation is indicated for end-stage cardiomyopathy when refractory to medical therapy, as well as previously repaired or palliated congenital heart disease when the individual has developed ventricular dysfunction or other non-operable late-term complications. An infant or child with complex congenital heart disease (e.g., pulmonary atresia with intact septum and coronary arterial stenosis, some forms of hypoplastic left heart syndrome) for whom standard surgical procedures are extremely high risk may also be an appropriate candidate for heart transplantation (Bernstein, 2016).

According to UNOS (2023a), the equity in access to heart transplants correspond to five key factors:

- Donation Service Area (DSA)
  - The DSA in which a candidate is listed is the factor most associated with unintended disparities in deceased donor heart transplant access
- Blood Type
  - blood type AB candidates have higher rates of transplantation and O candidates have the lowest rates of transplantation
- Age:
  - older candidates have higher rates of transplantation compared to younger candidates
- Height:
  - taller individuals have greater access to deceased donor transplantation

- Weight:
    - heavier individuals have less access to deceased donor transplantation

Differences associated with other factors beyond these five are relatively small.

The OPTN/SRTR 2021 Annual Data Report (July 2022) reported demographic trends in the heart transplant waiting list since 2010. According to the report, the largest age group on the waiting list in 2021 was 50-64 years, however, there has been a gradual decrease in this age group since 2010 made up 20.4% of the list in 2021, an increase from 16.5% in 2010. All other age groups have remained stable since 2016. Sex distribution has stayed relatively constant, with women constituting 24.9% in 2021. There has been an increasing prevalence of non-White candidates. UNOS reported that White candidates on the waiting list decreased from 69.4% in 2010 to 57.9% in 2021, Black candidates increased from 20.4% to 27.4%, Hispanic candidates (includes those who are categorized as White and Hispanic or solely Hispanic) increased from 7.0% to 10.1% and Asian candidates have similarly increased, making up 3.6% of candidates in 2021.

Heart transplant rates have increased over the past decade with the greatest 10-year increases occurring in those with the following features: aged 65 years or older, White, congenital heart disease, blood type B, female, and height of 150-< 160 cm. Since 2017, there has been noticeable increases (49.2% or greater) in those who are aged 65 years or older, who are Asian or Hispanic, who have congenital heart disease or coronary artery disease, with blood type AB or B, and who are 150-< 160 cm tall. Patients aged 35–49 years, 180 cm or taller, Black race, those with congenital heart disease, and those of blood type O undergo transplant at substantially lower rates than others in their categories.

The pretransplant mortality rate has been stable since 2019. There was a large decline in pretransplant mortality among those aged 18–34, who now have the lowest mortality rate of all age groups. Pretransplant mortality in candidates aged 65 years or older remains slightly higher than in other age groups. Valvular heart disease and other (as diagnosis) tend to have higher pretransplant mortality relative to other diagnoses. Despite having the lowest transplant rate of the diagnosis groups, patients with congenital heart disease also tend to have the lowest pretransplant mortality. Since 2017 pretransplant mortality has trended slightly higher among candidates who reside in non-metropolitan areas.

The number of heart transplants increased across all ages, sexes, races and ethnicities, and causes of heart failure except valvular heart disease from 2010 to 2021. When compared with adult heart transplant recipients in 2011, adult recipients in 2021 were older, more often male, and more often White, although there were more non-Whites than in 2011. The five-year survival is comparable between age groups. During the first year of transplant, those aged 65 years or older had the greatest decrease in survival and Hispanic recipients had an early decline in survival from 99.7% to 88.0% in the first year. Patients categorized as other race and ethnicity tended to have a slight survival advantage throughout five years.

Literature Review for Heart Transplantation: Heart transplantation is considered a standard of care for selected individuals. No prospective randomized study comparing heart transplantation to optimal medical therapy has been reported; however, several retrospective reviews and database analyses have demonstrated improved long-term outcomes with heart transplantation for selected individuals (OPTN/SRTR 2021 Annual Data Report, 2023; Deuse, et al., 2008; Tjang, et al., 2008; Weiss, et al., 2008).

Professional Societies/Organizations
American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA): 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).

American College of Cardiology/American Heart Association Task Force on Practice Guidelines/Heart Failure Society of America (ACC/AHA/HFSA): 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.

American Heart Association (AHA): A 2020 ACC/AHA guideline for the diagnosis and treatment of hypertrophic cardiomyopathy (HCM) (Ommen, et al., 2020) stated that patients with advanced heart failure (NYHA functional class III to class IV despite guideline-directed therapy) and nonobstructive HCM or with life-threatening ventricular arrhythmias refractory to maximal guideline directed therapy should be assessed for heart transplantation. Symptomatic children with HCM with restrictive physiology who are not responsive to, or appropriate candidates for, other therapeutic interventions should be considered for heart transplantation.

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 with the partial (lobar) or whole lung or lungs of a living or deceased donor. 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 (Orens, et al., 2006).

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. As donor organs are scarce relative to the number of candidates needing transplantation, conservation of acceptable donor organs is also taken into consideration.

According to UNOS (2023a), the equity in access to lung transplants correspond to four key factors:

- Donation service area (DSA):
  - the DSA in which a candidate is listed is the factor most associated with unintended disparities in deceased donor lung transplant access
- Height
  - taller adults were found to have moderately greater access to lung transplants
- Weight
  - heavier individuals were found to have less access to deceased donor transplantation
- Race/Ethnicity
  - Black Non-Hispanic, Hispanic/Latino, and Asian Non-Hispanic candidates were found to have lower rates of lung transplantation than Other/Multiracial Non-Hispanic and White Non-Hispanic candidates

Differences associated with other factors are relatively small.

The OPTN/SRTR 2021 Annual Data Report (2023) stated that the proportion of candidates identifying as White race on the waiting list for a lung transplant has declined to 68.6%, a 15.4% decline since 2010, whereas the proportion of candidates identifying as Black race has increased to 11.3% and Hispanic ethnicity to 14.7%, increases of 13.6% and 137.4%, respectively. There continues to be a higher percentage of men than women waiting for a lung transplant. Since 2010, the proportion of patients on the waiting list 65 years or older increased by 67.0% compared with 2010.

Patients 65 years and older had the greatest pretransplant mortality rate. Pretransplant mortality was greater for men compared to women, and varied by by race, blood type, and height, although these findings are influenced by small group numbers. The majority, of donors were 18-54 years old. There was 39.3% of donors that were women, 58% of donors were White; 19.1%, Hispanic; 18.7%, Black; and 2.9%, Asian. The overall rate of lungs recovered for transplant but not transplanted was 8.1%, with the highest rates for donors aged 55 years or older. In 2020, 5.4% lungs were recovered for transplant and not transplanted.

The largest number of transplants (1,171) occurred in recipients aged 50–64 years, followed by 933 in those aged 65 years or older, with 440 transplants in recipients aged 18–49 years. More transplants occurred in males compared with females, in the context of a higher proportion of male candidates listed for transplant and a higher waitlist mortality compared with females. There were fewer transplants in White recipients, with small increases in transplants for Black, Hispanic, and Asian recipients. White recipients accounted for 70.6% of transplants; Hispanic, 13.9%; Black, 10.1%; and Asian, 4%. Five-year posttransplant survival was lowest for recipients aged 65 and older.

Deceased Donor Lung Transplantation: A deceased donor, also known as cadaveric donor, is the most common donor source used for lung transplantation. Deceased donors are categorized into either donation after brainstem death (DBD) or donation after circulatory death (DCD). The management of the donation after brain death (DBD) donor includes optimizing cardiac filling pressures, maintaining adequate arterial pressure for donor organ perfusion, ensuring a patent airway and maintaining protective ventilation strategies, and maintaining metabolic homeostasis. DCD donor lungs are proposed to increase lung transplant activity, decreasing duration on the waiting list and waitlist mortality. The standard criterion for determination of circulatory death is the permanent absence of respiration and circulation. Because circulatory death occurs in differing circumstances, the severity of the ischemic injury to the donor lungs may vary. DCD grafts sustain a greater degree of ischemic insult prior to harvesting when they are subsequently cooled and perfused. This is because, during DBD, organs undergo cold perfusion prior to organ harvesting, whilst in DCD grafts there is a definitive period between cardiac arrest and organ retrieval. This

period is known as the "warm ischemic time" and has been shown to affect organ quality. When lungs are transported, the lungs are flushed and then preserved in a cold storage device for transport to their destination hospital. The lungs are cooled to prevent damage ex vivo before being gradually warmed for placement into the recipient. Cold storage is based around the concept that it slows metabolism, reduces oxygen consumption and substrate requirements thus preventing end organ deterioration. In 2021 there were 2346 DBD donations and 198 DCD donations in transplant candidates aged 12 years or older (OPTN/SRTR 2021 Annual Data Report, 2023; Copeland, et al., 2020; Jin, et al., 2020;).

In 2023 OPTN updated the policy on the allocation of lungs based on continuous distribution. Continuous distribution was developed to improve waitlist mortality and provide more lung transplants to the most medically urgent candidates. Each lung transplant candidate will receive a composite allocation score (CAS) for each organ offer.

The lung composite allocation score measures the following:

- candidate medical urgency (i.e., expected waitlist survival, maximum 25 points)
- likelihood of recipient survival over five years post-transplant (maximum 25 points)
- potential biological challenges in matching (e.g., blood type, height, immune sensitivity, maximum 15 points)
- whether the candidate was younger than age 18 years when listed for a transplant (20 points)
- whether the candidate was a prior living organ donor (5 points)
- placement efficiency, which is based on logistics of preserving and transporting the lungs between donor and transplant hospitals (maximum 10 points)

The people who have the highest number of points on a scale of 0–10 for that donor will be the first to get organ offers. The CAS replaces the previous Lung Allocation Score (LAS) for patients at least 12 years old. For patients < 12 years old, the current pediatric priority scores are integrated into the CAS medical urgency formula in addition to 20 pediatric points for being < 18 years old at the time of listing (OPTN policy, 2023; Hachem, 2023).

According to the Organ Procurement and Transplantation Network (OPTN) national data for deceased donor primary lung transplantation performed between 2008 and 2015, graft survival rates were 86.7%, 67.8% and 52.5%, respectively, at one-, three-, and five years (based on OPTN data as of July 14, 2023).

Living Donor Lung Transplantation (LDLT): Use of a live donor as a source for lung transplantation was initiated in 1993 due to the higher demand than supply for patients waiting for lung transplantation. Although LDLT may be appropriate for a highly selected individual who likely would not survive waiting times for a deceased donor, it is now rarely performed. According to the OPTN national data for lung transplant living donor, there were not any living donor lung transplants performed in from 2014-2023 (based on OPTN data as of July 14, 2023. This procedure requires the donation of one lung lobe from each of two living donors. Major complications have included pleural effusion, bronchial stump fistula, bi-lobectomy, hemorrhage phrenic nerve injury, pulmonary artery thrombosis, and bronchial stricture. Minor complications include persistent air leak, arrhythmia, and pneumonia. Deceased donor transplantation is preferred to avoid the risk to two healthy donors (Solomon, et al., 2010).

Indications for Lung Transplantation: Lung transplantation should be considered for adults with chronic, end-stage lung disease that has not responded to medical or surgical therapies.

The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates indicated that in addition to chronic, end-stage lung disease, there is general criteria to be met which included all of the following:

- 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

Additionally, there are disease specific considerations for which transplantation may be indicated. Along with examples of each category, these include (Leard, et al., 2021; Yusen, et al., 2016; Weill, et al., 2015):

- chronic obstructive lung disease (COPD) (e.g., alpha-1 antitrypsin deficiency, non alpha-1 antitrypsin deficiency)
- interstitial lung disease (ILD) (e.g., idiopathic pulmonary fibrosis (IPF), idiopathic interstitial pneumonia [IIP])
- cystic fibrosis (e.g., bronchiectasis)
- pulmonary arterial hypertension (e.g., primary/idiopathic pulmonary hypertension, Eisenmenger syndrome)
- lymphangioleiomyomatosis (LAM)
- acute respiratory distress syndrome (ARDS):

Disease-specific parameters used to determine appropriateness for lung transplantation have been suggested by the International Society for Heart and Lung Transplantation (ISHLT) (Yusen, et al., 2016; Weill, et al., 2015; Orens, et al., 2006), the American Society of Transplantation (Faro, et al., 2007; Steinman, et al., 2001) and other published scientific literature (Kotloff, 2010; Lynch, et al., 2006) and included the following (Leard, et al., 2021):

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

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

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

Literature Review for Lung Transplantation: Lung transplantation recipients represent a heterogeneous population, with different diagnostic groups having different survival rates; however, in a cohort study of 1997 patients, 1143 of whom received lung transplantation, improved survival was noted for all diagnosis groups (Titman, et al., 2009). Although there are no randomized controlled clinical trials demonstrating the safety and effectiveness of lung transplantation, several registry analyses and retrospective cohort studies note improved overall survival with transplantation compared with other medical and surgical therapies (OPTN/SRTR 2021 Annual Data Report, 2023; Chambers, et al., 2017; Christie, et al., 2010).

Professional Societies/Organizations
American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS): On behalf of the AST and ASTS, Faro et al. (2007) noted that, in general, lung transplantation should be considered in selected children with end-stage or progressive lung disease or life-threatening pulmonary vascular disease for which there is no other medical therapy.

Heart-Lung Transplantation
Heart-lung transplantation is the surgical replacement of the heart and lung(s) of an individual who has end-stage cardiopulmonary disease with the healthy heart and lungs of a donor. It is an accepted therapy for an individual whose disease is refractory to standard optimal medical or surgical treatment when no contraindications are present. Combined heart-lung transplantation is reserved for a candidate in whom either heart transplantation or lung transplantation alone will not improve the recipient's condition.

Indications for Heart-Lung Transplantation: Indications for heart-lung transplants have changed over time. During the time period January 2004 through June 2015 the most frequent indications for heart-lung transplant were congenital heart disease, pulmonary arterial

hypertension, and cardiomyopathy (Yusen, et al., 2016). Heart-lung transplantation is usually reserved for patients with uncorrectable or previously repaired or palliated congenital heart disease associated with significant pulmonary vascular obstructive disease. Such disease includes a single-ventricle physiology with pulmonary vascular disease or left ventricular (LV) dysfunction with associated pulmonary vascular disease. In the presence of more complex intracardiac abnormalities, combined heart-lung transplantation is usually most appropriate. Indications include, but are not limited to complex congenital disease, and pulmonary hypertension, either secondary to idiopathic pulmonary arterial hypertension or congenital heart disease (CHD). (Leard, et al., 2021; Bernstein, 2016; Warnes, et al., 2008).

Literature Review for Heart-Lung Transplantation: There are no randomized clinical trials comparing heart-lung transplantation to optimal medical treatment. Graft survival for primary heart-lung transplant recipients at one-, three- and five-years were 80.9%, 58.3% and 49.2%, respectively, based on Organ Procurement and Transplantation Network (OPTN) national data for primary heart-lung transplants performed 2008-2015 (based on OPTN data as of July 14, 2023)

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 (Goldraich, et al., 2016; Kawut, et al., 2008).

Re-transplantation has remained constant at 2%–4% of adult heart transplants since 1982. Cardiac allograft vasculopathy (CAV) and myopathy are the most common reasons for re-transplantation (Lund, et al., 2014). Heart re-transplantation is indicated for those patients who develop CAV with refractory cardiac allograft dysfunction, without evidence of ongoing rejection (Mehra, et al., 2016). Graft survival outcomes for repeat heart transplantation preformed between 2008 and 2015 are 86.5%, 75.5% and 67.9% for one-, three-, and five-years, respectively, based on Organ Procurement and Transplantation network (OPTN) national data as of July 14, 2023. Although outcomes are decreased for both children and adults compared to results for primary transplantation, re-transplantation may be an appropriate intervention for eligible children and adults.

Outcomes after repeat lung transplantation are generally poorer than those seen with the primary transplantation procedure. Survival rates for repeat lung transplantation performed between 2008 and 2015 were 76%, 48.9% and 32.9%, respectively, at one-, three-, and five-years (based on OPTN national data as of July 14, 2023). Although data are limited, lung re-transplantation may be an appropriate therapeutic option for highly selected individuals for complications of transplantation that are refractory to other medical or surgical therapies. Survival rates were not available for repeat heart-lung transplants at one, three and five years due to the low number of transplants performed.

Contraindications to Heart, Lung, and Heart-Lung Transplantation
Many factors affect the outcome of solid organ transplantation; appropriate selection is the first step in attaining the best result for each recipient. Transplantation of the heart, lung(s) or heart and lungs remains a complex therapy; it is important; therefore, to consider the sum of all contraindications and comorbidities.

Heart Transplantation Contraindications: In the 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update, the following contraindications are noted (Mehra, et al., 2016):

- diabetes with end-organ damage
- irreversible renal dysfunction (eGFR < 30 ml/min/1.73 m2)

- symptomatic cerebrovascular disease
- elevated pulmonary vascular resistance
- severe extracardiac amyloid organ dysfunction
- chronic HCV or HBV infection, clinical, radiologic or biochemical signs of cirrhosis, portal hypertension or hepatocellular carcinoma

Lung and Heart-Lung Transplantation Contraindications: In the consensus document for the selection of lung transplant candidates: an update from the International Society for Heart and Lung Transplantation (Leard, et al., 2021) the following contraindications are noted (list is not all inclusive):

- patient not willing to accept 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, myocardial infarction or 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, disseminated infection or 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 ongoing assessment of non-adherence
- substance use or dependence
- any other severe uncontrolled medical condition expected to limit survival after transplant

Use Outside of the US:
Canadian Cardiovascular Society/Canadian Cardiac Transplant Network Position Statement on Heart Transplantation: Patient Eligibility, Selection, and Post-Transplantation Care update on cardiac transplantation indicated that cardiac transplantation should be considered for eligible patients with advanced heart failure (HF) who are ≤ 70 years of age and for carefully selected patients with advanced HF > 70 years of age. Additionally, it is recommended to perform an assessment of frailty using the Fried Frailty Phenotype score, Deficit Index, or Edmonton Frailty Scale. Frailty in patients with advanced HF is associated with increased morbidity and mortality. The position statement indicated that the contraindications to heart transplant included: repeated medical nonadherence, active alcohol or drug abuse, active smoking, and mental health and social conditions that are likely to affect compliance. Furthermore, significant pulmonary hypertension (PH), defined as pulmonary vascular resistance > 3 Wood Units, transpulmonary gradient > 15 mm Hg and/or pulmonary artery systolic pressure > 50 mm Hg, is a contraindication for heart transplant because of greater risk of post transplantation right ventricular failure and early mortality (Chih, et al., 2020).

The Heart Failure Association (HFA) of the European Society of Cardiology (ESC) issued a position statement on advanced heart failure (Crespo-Leiro, et al., 2018) which indicated that heart transplantation remains the treatment of choice for patients with advanced or end-stage heart failure without contraindications. Data from the latest International Society for Heart and Lung Transplantation (ISHLT) Registry showed one-year survival of around 90% and median survival of 12.2 years. Transplantation not only improves survival but also functional status and quality of life (Lund, et al., 2014). Contraindications included active infection, severe peripheral

arterial/cerebrovascular disease, pharmacologic irreversible pulmonary hypertension, cancer, irreversible renal dysfunction, systemic disease with multi-organ involvement, other serious co-morbidity with poor prognosis, pre-transplant BMI > 35 kg/m^2, current alcohol or drug abuse and any patient for whom social supports are deemed insufficient.

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.
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
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
Annual review	• Updated to new template and formatting standards.	9/15/2023