Heart, Lung, and Heart-Lung Transplantation

Medically Necessary

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 with a functional status of New York Heart Association class III or IV 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. In each case, the candidate should meet all of the criteria for selection for the individual transplant being considered.

Not Medically Necessary or Experimental/Investigational/Unproven

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/mm³
  - 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)

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.

General Background

Heart Transplantation
Heart transplantation is the therapy of choice in adults with end-stage heart disease, 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 (Canter, 2007; Butler, 2004; Fishbein, 2001). According to the Organ Procurement and Transplantation Network (OPTN) policy/guideline, each heart transplant candidate is assigned a status that reflects the candidate’s medical urgency for transplant (OPTN, 2017):

- Adult status 1A, 1B, 2, or inactive for candidates at least 18 years old at the time of registration
- Pediatric status 1A, 1B, 2, or inactive for candidates less than 18 years old at the time of registration

Justification for adult heart status 1A and 1B includes having at least one of the following devices or therapies in place:

- left ventricular assist device (LVAD)
- right ventricular assist device (RVAD)
- left and right ventricular assist devices (BiVAD)
- continuous infusion of intravenous inotropes

Justification for pediatric heart status 1A and 1B includes patients admitted to the hospital that registered the candidate with at least one of the following criteria:

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

Requirements for pediatric heart status 1B include at least one of the following criteria:

- requires infusion of one or more inotropic agents but does not qualify for pediatric status 1A
- < 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 1997-2004 states that one-, three-, and five-year patient overall survival (OS) rates for primary transplantation were 87.1%, 78.5%, and 71.5 %, respectively (OPTN, 2014). Risk factors for mortality after transplantation include retransplantation, an intertransplant time (i.e., time between primary and retransplantation) of <180 days, the need for mechanical ventilation or ventricular assist device, use of a female donor, and the overall transplant center volume (Boucek, 2007; Canter, 2008; Mahle, 2008).

**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 nonoperative late-term complications. An infant or child with complex congenital heart disease (e.g., pulmonary atresia with intact septum and coronary arterial stenoses, 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, 2007).
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 (Deuse, 2008; Tjang, 2008; Weiss, 2008).


A 2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (HCM) (Gersh, 2011) notes patients with advanced (i.e., end-stage) heart failure and nonobstructive HCM not otherwise amenable to other treatment interventions with ejection fraction (EF) ≤ 50%, or occasionally with preserved EF, should be considered 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. In general, indications for heart transplantation include advanced heart disease, typically with NYHA functional class III or IV symptoms that are refractory to all other reasonable interventions. Heart transplantation should not be performed in mildly symptomatic patients of any age with HCM.

A 2008 ACCF/AHA Guideline for the Management of Adults with Congenital Heart Disease (Warnes, 2008) notes heart and heart-lung transplantation are reserved for severe systemic vascular failure with or without pulmonary artery hypertension when there is no surgical option. The Guideline also notes heart transplantation may be beneficial for severe systemic ventricular dysfunction or protein-losing enteropathy.

American Heart Association Council on Cardiovascular Disease in the Young, the Councils on Clinical Cardiology, Cardiovascular Nursing and Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group: Canter et al. (2007) published a joint statement on behalf of these professional societies that notes several recommendations for the use of heart transplantation for the treatment of heart disease as therapy for children with heart failure associated with systemic ventricular function in patients with cardiomyopathies or previously repaired or palliated congenital heart disease, those with severe limitation of exercise and activity, systemic ventricular dysfunction in patients with cardiomyopathies or previously repaired or palliated congenital heart disease when associated with significant growth failure attributable to the heart disease, and children with restrictive cardiomyopathy disease associated with reactive pulmonary hypertension.

The recommendation notes that in the presence of other indications for heart transplantation, this therapy is feasible in children with heart disease and an elevated pulmonary vascular resistance index > 6 Woods units/m and/or a transpulmonary pressure gradient > 15 mm Hg if inotropic support or pulmonary vasodilators can result in a decrease of these values.

Additionally, heart retransplantation is indicated in children with abnormal ventricular function and at least moderate graft vasculopathy, and those with normal ventricular function and at least moderate graft vasculopathy.

The recommendation also notes that retransplantation should not be performed during an episode of ongoing acute allograft rejection, even in the presence of graft vasculopathy. Further, retransplantation is not efficacious when performed during the first six months after primary transplantation.

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, 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.

**Deceased Donor Lung Transplantation:** A deceased donor, also known as cadaveric donor, is the most common donor source used for lung transplantation. In 1995, the United Network for Organ Sharing (UNOS) changed the method for allocating donated cadaver lungs for individuals >age 12 by assigning each candidate a Lung Allocation Score based on survival benefit and urgency rather than waiting time (Mulligan, 2008). In contrast, allocation to children under age 12 continues to be based on waiting time. Preferential transplantation of sicker patients has not resulted in an increase in early mortality following transplantation (Kotloff, 2010).

According to the Organ Procurement and Transplantation Network ([OPTN], 2014) national data for deceased donor primary lung transplantation performed between 1997 and 2004, graft survival rates were 83.1%, 62.1%, and 46.2%, respectively, at one-, three-, and five years (based on OPTN data as of July 4, 2014).

**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 annual report (2012), only one living donor lung transplant (LDLT) was performed in 2012 with four LDLT performed between 2007 and 2012. Survival data for LDLT performed in 2012 were not published in the annual report. 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 (Solomon, 2010). Deceased donor transplantation is preferred to avoid the risk to two healthy donors (Solomon, 2010).

**Indications for Lung Transplantation:** Four primary diagnostic groupings of lung disease for which transplantation may be indicated have been identified. Along with examples of each category, these include:

- chronic obstructive lung disease (COPD) (e.g., emphysema, alpha-1 antitrypsin deficiency)
- pulmonary vascular disease (e.g., primary pulmonary hypertension, Eisenmenger syndrome)
- cystic fibrosis or immunodeficiency disorders (e.g., cystic fibrosis, bronchiectasis, hypogammaglobulinemia)
- restrictive lung disease (e.g., idiopathic pulmonary fibrosis (IPF), also called cryptogenic fibrosing alveolitis, pulmonary fibrosis from other causes (e.g., fibrogenic dust, drug toxicity, or severe pulmonary hypertension, interstitial lung disease)

Disease-specific parameters used to determine appropriateness for lung transplantation have been suggested by the International Society for Heart and Lung Transplantation ([ISHLT]) (Orens, 2006), the American Society of Transplantation (Steinman, 2001; Faro, 2007), the American Society of Transplant Surgeons (Faro, 2007), and other published scientific literature (Kotloff, 2010; Lynch, 2006; Maurer, 2005; Trulock, 2004; Maurer, 2001) and include the following:

**Chronic Obstructive Airway Disease** (e.g., emphysema, chronic bronchitis and bronchiolitis obliterans):

- BODE (i.e., body mass index [B], degree of obstruction [O], dyspnea [D], exercise capacity [E]), score of 7–10 measured by a six-minute walk test.
- FEV1 (i.e., forced expiratory volume in the first second) less than 20%–25% of predicted, without reversibility; changed to FEV1 less than 20%–25% of predicted in in the 2014 guideline update (Weill, et al., 2015)
• history of hospitalization for exacerbation of COPD associated with acute hypercapnia (e.g. PCO₂ (i.e., partial pressure (tension) of carbon dioxide, artery) ≥50 mmHg)
• pulmonary hypertension and/or cor pulmonale, despite oxygen therapy
• elevated PaCO₂ (i.e., partial pressure (tension) of carbon dioxide, alveolar) with progressive deterioration requiring long-term oxygen therapy

Cystic Fibrosis and Other Bronchiectatic Diseases:
• FEV1 ≤30% of the predicted value
• rapidly declining lung function with FEV1 >30% predicted as evidenced by increasing numbers of hospitalizations, rapid fall in FEV1, or massive hemoptysis or increasing cachexia, despite medical management
• increasing frequency of exacerbations requiring antibiotic therapy
• refractory and/or recurrent pneumothorax
• oxygen-dependent respiratory failure
• hypercapnia
• pulmonary hypertension

Idiopathic Pulmonary Fibrosis (IPF): Histologic or radiographic evidence of IPF and any of the following:
• symptomatic (e.g., oxygen desaturation with rest or exercise), progressive disease with failure to improve or maintain lung function while being treated with steroids or other immunosuppressive drug therapy
• a 10% or greater decrease in FVC (i.e., forced vital capacity) during six months of follow-up
• diffusion capacity (corrected for alveolar volume) less than 39% predicted
• honeycombing on computerized tomography
• decrease in pulse oximetry <88% during a six-minute walk test

Sarcoidosis: These individuals have poor outcomes in the following clinical scenarios:
Impairment of exercise tolerance as evidenced by New York Heart Association (NYHA) functional class III or IV and any of the following:
• pulmonary hypertension
• hypoxemia at rest
• elevated right atrial pressure exceeding 15 mmHG (millimeters of mercury)

Pulmonary Arterial Hypertension:
• persistent NYHA functional class III or IV
• low, or declining six-minute walk test
• cardiac index of less than two liters per minute per square meter
• right atrial pressure of more than 15 mmHg
• mean pulmonary artery pressure greater than 55 mmHg

Primary Pulmonary Hypertension Secondary to Congenital Heart Disease (e.g., Eisenmenger syndrome):
• severe progression of symptoms with function at NYHA functional class III or IV, despite optimal medical management

Lymphangioleiomyomatosis and Eosinophilic Granuloma:
• NYHA functional class III or IV
• severe impairment in lung function and exercise capacity
• hypoxemia at rest
Cardiopulmonary Vascular Disease in Children:

- disease no longer responding to maximum medical and/or surgical treatment
- moderately severe or severe functional impairment (i.e., NYHA functional class III or IV)
- right ventricular failure
- severe cyanosis
- low cardiac output

Other Diseases in Children Presenting in Advanced Stages (e.g., bronchiolitis obliterans syndrome, pulmonary fibrosis and bronchopulmonary dysplasia):

- progressive disability (i.e., NYHA functional class III or IV) despite optimal medical therapy

A significant incidence of coronary artery disease is found in individuals with lung disease (Choong, 2006). Cardiac revascularization is a therapeutic option which may be used with lung transplantation for individuals with coronary artery disease that is amenable to percutaneous intervention or bypass grafting (Orens, 2006).

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, 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 (Organ Procurement and Transplantation Network [OPTN], 2013; Christie, 2009; Titman, 2009).

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: Congenital heart disease remains the most common indication for persons receiving heart-lung transplantation, followed by primary pulmonary hypertension (PPH). 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 (Warnes, 2008). Indications include, but are not limited to complex congenital disease with pulmonary hypoplasia, Eisenmenger syndrome, primary pulmonary hypertension, congenital lung abnormalities, alpha-antitrypsin deficiency, and end-stage parenchymal lung disease (Warnes, 2008; Bernstein, 2007; Gammie, 2001; Maurer, 2001).

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 66%, 48% and 38.2, respectively, based on Organ Procurement and Transplantation Network ([OPTN], 2014) data for primary heart-lung transplants performed 1997-2004 (based on July 4, 2014 data).
Professional Societies/Organizations: American College of Cardiology/American Heart Association (ACC/AHA): On behalf of the ACC/AHA, Warnes et al. (2008) published Updated Guidelines for the Management of Adults with Congenital Heart Disease, which notes that 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 or left ventricular dysfunction with associated pulmonary vascular disease. When a simple cardiac defect (e.g., atrial septal defect, ventricular septal defect, patent ductus arteriosus) is present, the defect can often be repaired at lung transplantation. In the presence of more complex intracardiac abnormalities, combined heart-lung transplantation is usually most appropriate.

Retransplantation
Retransplantation remains a controversial procedure, in part due to ethical concerns over the limited supply of organs. The recipient of the retransplantation procedure often suffers from the systemic sequelae of short- or long-term immunosuppression, infection, and technical issues attributable to the initial transplantation surgery (Kawut, 2008).

Retransplantation accounts for slightly greater than four percent of the total population of individuals undergoing heart transplantation. Within this population common causes of allograft failure are acute rejection, primary graft failure, or transplant arteriopathy (Atluri, 2008). Graft survival outcomes for repeat heart transplantation are 81.8%, 66.4%, and 57.8% for one-, three-, and five-years, respectively, based on Organ Procurement and Transplantation network (OPTN) data as of July 4, 2014. Heart retransplantation is indicated for those patients who develop significant cardiac allograft vasculopathy (CAV) with refractory cardiac allograft dysfunction, without evidence of ongoing rejection (Mehra, et al., 2016) Although outcomes are decreased for both children and adults compared to results for primary transplantation, retransplantation 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 1997 and 2004 were 65%, 39.3%, and 27.5%, respectively, at one-, three-, and five-years (based on OPTN data as of July 4, 2014). Although data are limited, lung retransplantation may be an appropriate therapeutic option for highly selected individuals for complications of transplantation that are refractory to other medical or surgical therapies. One-year survival rates for repeat heart-lung transplantation performed between 1997 and 2004 were 48%. Survival rates were not available for 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.

Absolute contraindications include 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, untreatable advanced dysfunction of another organ system, 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 transplant, a pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure, and human immunodeficiency virus (HIV) disease unless in selected individuals.

The presence of several relative contraindications can combine to increase morbidity and mortality (Orens, 2006). Relative contraindications to transplantation include, but are not limited to (Acker, 2011; Mehra, 2006; Maurer, 2005; Fishbein, 2001; Gammie, 2001; Steinman, 2001):
- current, ongoing substance abuse, including tobacco, alcohol and narcotic/other addictive pain medications
- cerebrovascular disease or accident, or progressive neuropathy or myopathy that is not amenable to rehabilitation
- body mass index (BMI) less than 17 or greater than 33
• any active medical process that is currently not optimally treated and/or stable and that is likely to result in end-organ damage or medical emergency without appropriate management, such as active peptic ulcer disease, diverticular disease, active hepatitis, cholecystitis, pancreatitis, hypertension, autoimmune disease, or cytopenia
• severe or symptomatic osteoporosis with a T-score greater than 2.5 standard deviations (SD) from mean or Z-score greater than two SD from mean
• hepatic fibrosis or cirrhosis
• hepatitis C with biopsy-proven, histologic evidence of hepatic disease
• uncorrected abdominal aortic aneurysm greater than four centimeters
• diabetes mellitus with end-organ damage, such as neuropathy, nephropathy or retinopathy
• advanced age
• peripheral vascular disease not amenable to surgical or percutaneous therapy as evidenced by:
  ➢ asymptomatic stenosis greater than 75% or symptomatic carotid stenosis of less severity
  ➢ ankle brachial index less than 0.7 or substantial risk of limb loss with diminished perfusion
• critical or unstable clinical condition (e.g. shock, mechanical ventilation or extracorporeal membrane oxygenation)
• colonization with highly resistant or highly virulent bacteria, fungi or mycobacteria

Additionally, there are other conditions that may affect the outcome of heart, lung, or heart-lung transplantation and require further investigation to ensure the best chance for a successful outcome:

**Heart Transplantation:**

• advanced heart failure in the setting of advanced irreversible end-stage renal disease
• severe obstructive or restrictive lung disease, as evidenced by pulmonary function testing (FEV1 <1.51 liters)
• recent pulmonary embolism or infarction
• irreversible pulmonary hypertension, as evidenced by:
  ➢ elevated pulmonary artery pressures (>65 mmHg) despite vasodilators or inotropes
  ➢ elevated transpulmonary gradient (>15 mmHg) despite treatment
• elevated pulmonary vascular resistance (PVR) (>six Wood units) despite vasodilators or inotropes (in children, an elevated pulmonary vascular resistance index >six Woods units requires additional investigation and optimization of the medical regimen [Addonizio, 2001])

**Lung and Heart-Lung Transplantation:**

• progressive neuromuscular disease
• prednisone use greater than 20 mg per day or 40 mg every other day
• recent pulmonary embolism/infarction
• mechanical ventilation
• previous major thoracic surgery or pleural procedures
• colonization with pan-resistant organisms, especially Burkholderia cepacia
• primary systemic disease, such as amyloidosis

**Use Outside of the US:**
**Canadian Cardiovascular Society Consensus (2009):** On behalf of the Society, Haddad et al. notes “Cardiac transplantation is the treatment of choice for patients who have severe end-stage heart failure despite maximal medical therapy and/or complex congenital heart disease not amenable to surgical palliation at reasonable risk. In general, patients with extracardiac disease that would significantly reduce their expected lifespan, or that would be exacerbated by the post-transplant use of immunosuppressive agents, are not candidates for transplantation, nor are patients without significant rehabilitation potential.”
Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation (ISHLT): On behalf of the ISHLT, Orens et al. (2006) noted that lung transplantation is an appropriate treatment option for end-stage pulmonary disease when alternative maximum medical and surgical options have failed. Selection of the type of donor (i.e., cadaveric or living donor) and the type of transplant (i.e. single, double or lobar) is dependent on the patient’s diagnosis, clinical status, and availability of the donor organ. In the International Guidelines for Selection of Lung Transplant Candidates: 2006 Update—A Consensus Report from the Pulmonary Scientific Council of the ISHLT (Orens, 2006), the following absolute contraindications are noted:

- Malignancy in the last 2 years, with the exception of cutaneous squamous and basil cell tumors. In general, a 5-year disease-free interval is prudent. The role of lung transplantation for localized bronchioalveolar cell carcinoma remains controversial.

- Untreatable advanced dysfunction of another major organ system (e.g., heart, liver, or kidney). Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function, is an absolute contraindication to lung transplantation, but heart-lung transplantation could be considered in highly selected cases.

- Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B, hepatitis C, and human immunodeficiency virus.

- Significant chest wall deformity.

- Documented nonadherence or inability to follow through with medical therapy and/or office follow-up.

- Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy.

- Absence of a consistent or reliable social support system.

- Substance addiction (e.g., alcohol, tobacco, narcotics) that is either active or within the last 6 months; changed to “substance abuse or dependence (e.g., alcohol, tobacco, marijuana, or other illicit substances)” in the 2014 guideline update (Weill, et al., 2015).

The following relative contraindications are also noted:

- Age older than 65 years: older patients have less optimal survival, likely due to comorbidities, and therefore recipient age should be a factor in candidate selection. Although there cannot be endorsement of an upper age limit as an absolute contraindication (recognizing that advanced age alone in an otherwise acceptable candidate with few comorbidities does not necessarily compromise successful transplant outcomes), the presence of several relative contraindications can combine to increase the risks of transplantation above a safe level.

- Critical or unstable clinical condition (e.g., shock, mechanical ventilation or extracorporeal membrane oxygenation.

- Severely limited functional status with a poor rehabilitation potential; moved to absolute contraindications list in the 2014 guideline update (Weill, et al., 2015).

- Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.

- Severe obesity defined as a body mass index exceeding 30kg/m².

- Severe or symptomatic osteoporosis.
- Mechanical ventilation - carefully selected candidates on mechanical ventilation without other acute or chronic organ dysfunction, who are able to actively participate in a meaningful rehabilitation program, may be successfully transplanted.

- Other medical conditions that have not resulted in end-stage organ damage, such as diabetes mellitus, systemic hypertension, peptic ulcer disease, or gastroesophageal reflux should be optimally treated before transplantation. Patients with coronary artery disease may undergo percutaneous intervention before transplantation or coronary artery bypass grafting concurrent with the procedure.

### Coding/Billing Information

**Note:**
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:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>32850</td>
<td>Donor pneumonectomy(s) (including cold preservation), from cadaver donor</td>
</tr>
<tr>
<td>32851</td>
<td>Lung transplant, single; without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32852</td>
<td>Lung transplant, single; with cardiopulmonary bypass</td>
</tr>
<tr>
<td>32853</td>
<td>Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32854</td>
<td>Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass</td>
</tr>
<tr>
<td>32855</td>
<td>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</td>
</tr>
<tr>
<td>32856</td>
<td>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</td>
</tr>
<tr>
<td>33930</td>
<td>Donor cardiectomy-pneumonectomy (including cold preservation)</td>
</tr>
<tr>
<td>33933</td>
<td>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</td>
</tr>
<tr>
<td>33935</td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
</tr>
<tr>
<td>33940</td>
<td>Donor cardiectomy (including cold preservation)</td>
</tr>
<tr>
<td>33944</td>
<td>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</td>
</tr>
<tr>
<td>33945</td>
<td>Heart transplant, with or without recipient cardiectomy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2152</td>
<td>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</td>
</tr>
<tr>
<td>S2060</td>
<td>Lobar lung transplantation</td>
</tr>
<tr>
<td>S2061</td>
<td>Donor lobectomy (lung) for transplantation, living donor</td>
</tr>
</tbody>
</table>
References


“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2017 Cigna.