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

- Chronic obstructive pulmonary disease with heart failure
- Cystic fibrosis with severe heart failure
- Eisenmenger complex with irreversible pulmonary hypertension and heart failure
- Emphysema with severe heart failure
- Irreversible primary pulmonary hypertension with heart failure
- Nonspecific severe pulmonary fibrosis with severe heart failure
- Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure

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

Heart/lung transplantation is considered investigational in all other situations.

The factors below are potential contraindications subject to the judgment of the transplant center:

- History of cancer with a moderate risk of recurrence
- Known current malignancy, including metastatic cancer
- Other irreversible end-stage disease not attributed to heart or lung disease
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy
- Recent malignancy with high risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Untreated systemic infection making immunosuppression unsafe, including chronic infection

When the candidate is eligible to receive a heart in accordance with United Network for Organ Sharing (UNOS) guidelines for cardiac transplantation, the lung(s) shall be allocated to the heart/lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with the UNOS Lung Allocation System, the heart shall be allocated to the heart/lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart (Organ Procurement and Transplantation Network, 2017).

Specific criteria for prioritizing donor thoracic organs for transplant are provided by the Organ Procurement and Transplantation Network (OPTN) and implemented through a contract with UNOS. Donor thoracic organs are prioritized by UNOS on the basis of recipient medical urgency, distance from donor hospital, and pediatric status. Patients who are most severely ill (status 1A) are given highest priority.

The following factors are considered in assessing the severity of cardiac illness: reliance on continuous mechanical ventilation, infusion of intravenous inotropes, and/or dependency on mechanical circulatory support (i.e., total artificial heart, intra-aortic balloon pump, extracorporeal membrane oxygenator, ventricular assist device). Factors considered in assessing the severity of pulmonary illness include increased pulmonary artery systolic pressure (>60 mm Hg), pulmonary arterial hypertension, and/or elevated pulmonary vascular resistance.
Additional criteria may be considered in pediatric patients, including diagnosis of an OPTN-approved congenital heart disease diagnosis, presence of ductal dependent pulmonary or systemic circulation, and diagnosis of hypertrophic or restrictive cardiomyopathy while less than 1 year old. Of note, pediatric heart transplant candidates who remain on the waiting list at the time of their 18th birthday without receiving a transplant continue to qualify for medical urgency status based on the pediatric criteria.

In both adult and pediatric patients, isolated cardiac or pulmonary transplantations are preferred to combine heart/lung transplantation when medical or surgical management—other than organ transplantation—is available.

Full OPTN guidelines are available online (at https://optn.transplant.hrsa.gov/governance/policies/).

Status 7 patients are considered temporarily unsuitable to receive a thoracic organ transplant.

**Description**

Heart/lung transplantation involves a coordinated triple operative procedure consisting of procurement of a donor heart/lung block, excision of the heart and lungs of the recipient, and implantation of the heart and lungs into the recipient. Heart/lung transplantation refers to the transplantation of one or both lungs and heart from a single cadaver donor.

**Related Policies**

- Heart Transplant
- Lung and Lobar Lung Transplant

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

Heart/lung transplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

**Rationale**

**Background**

Combined heart/lung transplantation is intended to prolong survival and improve function in patients with end-stage cardiac and pulmonary diseases. Most recipients have Eisenmenger syndrome (37%), followed by idiopathic pulmonary artery hypertension (28%) and cystic fibrosis (14%). Eisenmenger syndrome is a form of congenital heart disease in which systemic-to-pulmonary shunting leads to pulmonary vascular resistance. It is possible that pulmonary
hypertension could lead to a reversal of the intracardiac shunting and inadequate peripheral oxygenation, or cyanosis.\textsuperscript{1}

Due to corrective surgical techniques and improved medical management of pulmonary hypertension, the total number of patients with Eisenmenger syndrome has seen a decline in recent years. Additionally, heart/lung transplants have not increased appreciably, but for other indications it has become more common to transplant a single or double lung and maximize medical therapy for heart failure, rather than perform a combined transplant. For those indications, patient survival rates following heart/lung transplantations are similar to lung transplant rates. Bronchiolitis obliterans syndrome is a major complication. One-, 5-, and 10-year patient survival rates for heart/lung transplants performed between 1982 and 2014 were estimated at 63%, 45%, and 32%, respectively.\textsuperscript{2}

In 2016, 18 individuals received heart/lung transplants in the United States. As of the end of July 2017, 38 patients were on the waiting list for heart/lung transplants.\textsuperscript{3}

**Literature Review**
Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

Due to the nature of the population, there were no randomized controlled trials comparing heart/lung transplant with alternatives. Systematic reviews were based on case series and registry data. The extant randomized controlled trials compare surgical technique, infection prophylaxis, and immunosuppressive therapy and are not germane to this evidence review. The following is a summary of evidence based on registry data, case series, and expert opinion.

**Combined Heart/Lung Transplant**
**Prioritization of Candidates**
Patients who are eligible for heart/lung transplantation can be listed under both the heart and lung allocation systems in the United States. In 2005, United Network for Organ Sharing (UNOS) changed the method by which lungs were allocated, from one based on length of time on the waiting list to a system that incorporates the severity of the patient’s underlying disease, as well as likelihood of survival.\textsuperscript{4} However, it has been noted that the individual systems underestimate the severity of illness in patients with both end-stage heart and lung failure, and modification of the lung allocation score can be appealed for patients who meet the following criteria:\textsuperscript{5}

- Deterioration on optimal therapy
- Right arterial pressure greater than 15 mm Hg
- Cardiac index less than 1.8 L/min/m\textsuperscript{2}

Specific criteria for prioritizing donor thoracic organs for transplant are provided by the Organ Procurement and Transplantation Network (OPTN) and implemented through a contract with UNOS.\textsuperscript{6}

Yusen et al (2016) analyzed data on heart/lung transplantations performed among adults between 1982 and 2015 using the registry of the International Society for Heart and Lung Transplantation (ISHLT).\textsuperscript{2} Among the 3397 heart/lung transplant recipients whom diagnosis was reported, 35% had congenital heart disease (CHD), 27% had pulmonary arterial hypertension, and 14% had cystic fibrosis as the primary indication. There has been a shift in indications for heart/lung transplantation over time. From 2004 to 2015, CHD (35%), pulmonary arterial
hypertension (27%), and cardiomyopathy (11%) were the three most common indications for heart/lung transplantation. Of the 883 heart/lung transplant recipients during 2004 and 2015, 36% were 18 to 34 years old, 40% were 35 to 49 years old, and 24% were 50 years or older.

**Pediatric Considerations**

According to ISHLT, among the 710 pediatric heart/lung transplant recipients during 1985 and 2015, 63% were 11 to 17 years of age, 19% were 6 to 10 years of age, 16% were 1 to 5 years of age, and 3% were less than 1 year of age. CHD (33%), cystic fibrosis (27%), and pulmonary arterial hypertension (26%) were the most common diagnoses among the pediatric heart/lung transplant recipients during this period.

A 2014 analysis of data from the Organ Procurement and Transplantation Network provided indications for pediatric heart/lung transplantation. The number of pediatric heart/lung transplants has decreased in recent years (56 cases from 1993 to 1997; 32 cases from 2008 to 2013). The 3 most common indications for pediatric heart/lung transplant were primary pulmonary hypertension (n=55), CHD (n=37), and Eisenmenger syndrome (n=30). However, while 30 children received a heart/lung transplant for Eisenmenger syndrome through 2002, no transplants for this syndrome have been performed since then. Pediatric heart/lung transplants have also been performed for other indications, including alpha-1-antitrypsin deficiency, pulmonary vascular disease, cystic fibrosis, and dilated cardiomyopathy.

In 2012, the ISHLT registry reported on pediatric heart/lung transplant data collected through June 2011. Overall survival rates after heart/lung transplants are comparable in children and adults (with a median half-life of 4.7 and 5.3 years, respectively). For pediatric heart/lung transplants that occurred between 1990 and 2010, the 5-year survival rate was 49%. The 2 leading causes of death in the first year after transplantation were non-cytomegalovirus infection and graft failure. Beyond 3 years posttransplant, the major cause of death was bronchiolitis obliterans syndrome. An updated 2014 report on pediatric lung and heart/lung transplant from the same registry did not include updated data on pediatric heart/lung transplants due to the small number of patients available.

**Initial Heart/Lung Transplantation Survival**

Yusen et al (2016) reported on the survival of adult heart/lung transplant recipients using the ISHLT database. Among the 3775 primary heart/lung transplants performed during 1982 and 2014, the 3-month, 1-year, 3-year, 5-year, and 10-year survival rates were 71%, 63%, 52%, 45%, and 32%, respectively. The overall median survival during this period (1982-2014) was 3.4 years. Those who survived to 1 year had a conditional median survival of 10.3 years. Survival improved over time, with a median survival of 2.1 years for patients (n=1596) who received transplant between 1982 and 1993, 3.9 years for patients (n=1392) between 1994 and 2003, and 5.8 years for patients between 2004 and 2014 (n=843) (p<0.05 for all pairwise comparisons). Heart/lung transplant recipients in the 2004 to 2014 group had a median conditional survival beyond 10 years. Compared with lung-only transplantation (median conditional survival, 8.0 years), heart/lung transplant recipients had a better long-term survival (median conditional survival, 10.3 years).

Hill et al (2015) compared survival following heart/lung transplantation with double-lung transplantation for idiopathic pulmonary arterial hypertension among adult transplant recipients in the Scientific Registry of Transplant Recipients database during 1987 and 2012. Among the 928 idiopathic pulmonary arterial hypertension patients, 667 underwent double-lung transplantation, and 261 underwent heart/lung transplantation. Overall, the adjusted survival was similar between double-lung transplantation and heart/lung transplant recipients. However, for recipients hospitalized in the intensive care unit, double-lung transplantation was associated with worse outcome compared with heart/lung transplantation recipients (hazard ratio [HR], 1.83; 95% confidence interval [CI], 1.02 to 3.28).
Jayarajan et al (2014) compared the mortality rates (at 1 month posttransplant and 5 years posttransplant) of heart/lung transplant recipients who required pretransplant ventilation (n=22) or extracorporeal membrane oxygenation (ECMO; n=15) with controls.12 The median time of survival was 10 days, 181 days, and 1547 days among patients with pretransplant ECMO, patients with mechanical ventilator, and the control group, respectively. Patients with pretransplant ECMO had a worse survival than the control group at 30 days (20.0% vs 83.5%) and 5 years (20.0% vs 47.4% p<0.001). Similarly, patients requiring ventilation prior transplantation had worse survival at 1 month (77.3% vs 83.5%) and 5 years (26.5% vs 47.4% p<0.001) compared with the control group. The use of ECMO (HR=3.82; 95% CI, 1.60 to 9.12; p=0.003) or mechanical ventilation (HR=2.01; 95% CI, 1.07 to 3.78; p=0.030) as a bridge to transplantation was independently associated with mortality on multivariate analysis. The findings of the study raise questions whether combined heart/lung transplant should be carried out in patients requiring ECMO; further, the findings suggest a need for additional research to improve survival in this high-risk group of patients.

Pediatric Considerations
Goldfarb et al (2016) reported on the survival of pediatric lung and heart/lung transplant recipients using the ISHLT database.13 Among the 698 pediatric heart/lung transplant recipients, median survival was 3.0 years, and conditional median survival was 7.8 years. There was no statistically significant difference in survival by indication, recipient age group, or time period of transplant for pediatric heart/lung transplant recipients.

Keeshan et al (2014) assessed outcomes for pediatric heart/lung transplantation between children who had CHD with and without Eisenmenger syndrome using the UNOS database of heart/lung transplantsations performed from 1987 to 2011.14 Among the 178 pediatric heart/lung transplantsations performed during that period, 73 (41%) had cardiac etiologies and 69 (38%) had idiopathic pulmonary arterial hypertension as the primary diagnosis. Among the patients with cardiac etiologies, CHD was the most common diagnosis (n=65). Children with CHD without Eisenmenger syndrome (n=34) had a lower median survival (1.31 years) than children with CHD plus Eisenmenger syndrome (n=31; median survival, 4.80 years; p=0.05). On multivariable analysis, CHD without Eisenmenger syndrome (adjusted HR=1.69; 95% CI, 1.09 to 2.62), younger age (adjusted HR=1.04; 95% CI, 1.01 to 1.08), pretransplant mechanical ventilation (adjusted HR=1.75; 95% CI, 1.01 to 3.06), pretransplant ECMO (adjusted HR=3.07; 95% CI, 1.32 to 7.12), pretransplant panel reactive antibodies (adjusted HR=1.53; 95% CI, 1.06 to 2.20), and transplant era (adjusted HR=1.85; 95% CI, 1.16 to 2.94) were associated with graft failure.

Section Summary: Initial Heart/Lung Transplant
Data from transplantation registries have found longer patient survival rates after initial heart/lung transplant among adult and pediatric patients over time (e.g., 5-year survival rate, 78%). The net benefit of heart transplantation compared with lung-only transplantation is also evident, especially among patients with idiopathic pulmonary arterial hypertension.

Heart/Lung Retransplantation Survival
While uncommon, repeat heart/lung transplant procedures have been performed. In 2014, Yusen et al reported on outcomes for adult heart/lung transplants, with a focus on retransplantation, using data from the ISHLT Registry.15 From 1982 to 2012, 90 adults had a first heart/lung retransplant after a previous heart/lung transplant. These 90 patients had a median survival of 0.3 year, with unadjusted survival rates of 52%, 43%, 36%, and 27% at 3 months, 1 year, 3 years, and 5 years, respectively. Those who survived to 1 year had a conditional median survival of 7.9 years.

A 2008 study, published by Shuhaiber et al, involved a review of data from the UNOS registry.16 They identified 799 primary heart/lung and 19 repeat heart/lung transplants. Using Kaplan-Meier survival analysis, the observed median survival times were 2.08 years after primary transplant and 0.34 years after repeat transplants. In addition, reviewers analyzed survival data in matched
pairs of primary and repeat transplant patients, who were matched on a number of potentially confounding demographic and clinical characteristics. Matches were not available for 4 repeat transplant patients. For the 15 repeat transplant patients with primary transplant matches, survival time did not differ significantly between the 2 groups. Being on a ventilator was statistically significantly associated with decreased survival time. The main limitation of this analysis was the low number of repeat transplant procedures performed.

**Section Summary: Heart/Lung Retransplant**
Analysis has suggested that patients undergoing heart/lung retransplantation have a lower median survival compared with patients undergoing primary heart/lung transplantation. However, after controlling of confounding variables, survival times did not differ significantly between groups. Also, the conditional mean survival of 7.9 years among those who survived to 1 year posttransplant would suggest a survival benefit of heart/lung retransplant.

**Potential Contraindications to Heart/lung Transplant (Applies to All Indications)**
Individual transplant centers may differ in their guidelines, and individual patient characteristics may vary within a specific condition. In general, heart transplantation is contraindicated in patients who are not expected to survive the procedure, or in whom patient-oriented outcomes (e.g., morbidity, mortality) are not expected to change due to comorbid conditions unaffected by transplantation (e.g., imminently terminal cancer, or other disease). Further, consideration is given to conditions in which the necessary immunsuppression would lead to hastened demise, such as active untreated infection. However, stable chronic infections have not always been shown to reduce life expectancy in heart transplant patients.

**Malignancy**
Pretransplant malignancy is considered a relative contraindication for heart transplantation given that malignancy has the potential to reduce life expectancy and could prohibit immune suppression after transplantation. However, with improved cancer survival over the years and use of cardiotoxic chemotherapy and radiotherapy, the need for heart transplantation has increased in this population.

Mistiaen et al (2015) conducted a systematic review to study the posttransplant outcome of pretransplant malignancy patients. Most selected studies were small case series (median sample size, 17 patients; range, 7-1117 patients; mean age, 6-52 years).17 Hematologic malignancy and breast cancer were the most common types of pretransplant malignancies. Dilated, congestive, or idiopathic cardiomyopathy were the most common reasons for transplantation in 4 case series, chemotherapy-related cardiomyopathy was the most important reason for transplantation. Hospital mortality ranged between 0% and 33%, with small sample sizes potentially explaining the observed variation. One large series (2012) reported similar short- and long-term posttransplant survival of chemotherapy-related (n=232) and other nonischemic cardiomyopathy (n=8890) patients.18 The 1-, 3-, and 5-year survival rates were 86%, 79% and 71% for patients with chemotherapy-related cardiomyopathy compared with 87%, 81% and 74% for other transplant patients, respectively. Similar findings were observed for 1-year survival in smaller series. Further, 2-, 5-, 10- and 15-year survival rates among pretransplant malignancy patients were found to be comparable with other transplant patients. In addition to the non-malignancy-related factors such as cardiac, pulmonary, and renal dysfunction, 2 malignancy-related factors were identified as independent predictors of 5-year survival. A malignancy-free interval (the interval between treatment of cancer and heart transplantation) of less than 1 year was associated with lower 5-year survival (<60%) than with a longer interval (>75%). Patients with prior hematologic malignancies had an increased posttransplant mortality in 3 small series. Recurrence of malignancy was more frequent among patients with a shorter disease-free interval, 63%, 26%, and 6% among patients with less than 1 year, 1 to 5 years, and more than 5 years of disease-free interval, respectively.19

Yoosabai et al (2015) conducted a retrospective review among 23,171 heart transplant recipients in the OPTN/UNOS database to identify whether pretransplant malignancy increases
the risk of posttransplant malignancy. Posttransplant malignancy was diagnosed in 2673 (11.5%) recipients during the study period. A history of any pretransplant malignancy was associated with increased risk of overall posttransplant malignancy (subhazard ratio [SHR], 1.51; p<0.01), skin (SHR=1.55; p<0.01), and solid organ malignancies (SHR=1.54; p<0.01) on multivariate analysis.

**Recurrence Risk**
The evaluation of a candidate who has a history of cancer must consider the prognosis and risk of recurrence from available information including tumor type and stage, response to therapy, and time since therapy was completed. Although evidence is limited, patients in whom cancer is thought to be cured should not be excluded from consideration for transplant. The ISHLT guidelines have recommended stratifying each patient with pretransplant malignancy as to their risk of tumor recurrence and that cardiac transplantation should be considered when tumor recurrence is low based on tumor type, response to therapy, and negative metastatic workup. The guidelines also recommended that the specific amount of time to wait to transplant after neoplasm remission will depend on these factors and no arbitrary time period for observation should be used.

**Human Immunodeficiency Virus (HIV) Infection**
Solid organ transplant for patients who are HIV-positive was historically controversial, due to the long-term prognosis for HIV positivity and the impact of immunosuppression on HIV disease. The availability of highly active antiretroviral therapy has markedly changed the natural history of the disease.

Aguero et al (2016) reported on a review on heart transplantation among HIV-infected patients. Since 2001, 12 heart transplantations in patients with HIV infection have been reported and 3 patients acquired HIV after heart transplantation. Fourteen (93%) of these 15 patients were younger than 50 years of age, with cluster of differentiation 4 (CD4) counts greater than 200 cells/mm³, and all of them were taking antiretroviral therapy. Thirteen were alive with normal graft function at the end of follow-up. One patient had suboptimal adherence to antiretroviral therapy and died of multiorgan failure. The cause of death in the other patient was not reported. There are few data directly comparing outcomes for patients with and without HIV or for combined heart/lung transplants.

As of February 2013, the UNOS policy 4 on HIV-positive transplant candidates states: “A potential candidate for organ transplantation whose test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy.”

In 2015, the British HIV Association and the British Transplantation Society published joint guidelines on kidney transplantation in patients with HIV disease. These criteria may be extrapolated to other organs:
- Adherent with treatment, particularly antiretroviral therapy
- CD4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- No opportunistic infections for at least 6 months
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis or lymphoma

**Other Potential Contraindications**
Considerations for heart transplantation and lung transplantation alone may also pertain to combined heart/lung transplantation. For example, cystic fibrosis accounts for most pediatric candidates for heart/lung transplantation, and infection with *Burkholderia* species is associated with higher mortality in these patients.
Summary of Evidence
For individuals who have end-stage cardiac and pulmonary disease who receive combined heart/lung transplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. The available literature describes outcomes after heart/lung transplantation. Given the exceedingly poor expected survival rates without transplantation, this evidence is sufficient to demonstrate that heart/lung transplantation provides a survival benefit in appropriately selected patients. Transplant may be the only option for some patients with end-stage cardiopulmonary disease. Heart/lung transplant is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or for whom posttransplantation care is expected to worsen comorbid conditions significantly. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a combined heart/lung transplant complicated by graft failure or severe dysfunction of the heart/lung and who receive a combined heart/lung retransplant, the evidence includes case series and registry data. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity and mortality. A very limited amount of data has suggested that, after controlling for confounding variables, survival rates after primary and repeat heart/lung transplants are similar. Findings are not conclusive due to the small number of cases of repeat heart/lung transplants reported in the published literature. Repeat heart/lung transplantation is, however, likely to improve outcomes in patients with a prior failed transplant who meet the clinical criteria for heart/lung transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information
Practice Guidelines and Position Statements
The International Society for Heart and Lung Transplantation issued consensus-based guidelines on the selection of lung transplant recipients in 1998, 2006,23 and most recently updated in 2014.24 These guidelines made the following statements about lung transplantation:

“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 surviving at least 90 days after lung transplantation.
- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function.”

For combined heart/lung transplant, the guidelines have stated that patients with irreversible myocardial dysfunction or irreparable congenital defects in conjunction with intrinsic lung disease or severe pulmonary arterial hypertension are appropriate candidates for heart/lung transplantation. The guideline also mentioned that isolated bilateral lung transplantation is associated with comparable or better outcomes in most patients with pulmonary hypertension associated with right ventricular failure.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Heart/lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria.25 The Centers for Medicare & Medicaid Services has stated that, under certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures safety and efficacy objectives.
Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

References


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**Documentation for Clinical Review**

**Please provide the following documentation (if when requested):**

- Referring physician history and physical
- Cardiology and pulmonary consultation report and/or progress notes documenting:
  - Diagnosis (including disease staging) and prognosis
  - Synopsis of alternative treatments performed and results
  - Specific transplant type being requested
- Surgical consultation report and/or progress notes
- Results of completed transplant evaluation including:
  - Clinical history
  - Specific issues identified during the transplant evaluation
  - Consultation reports/letters (when applicable)
  - Correspondence from referring physicians (when applicable)
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- Medical social service/social worker and/or psychiatric (if issues are noted) evaluations including psychosocial assessment or impression of patient's ability to be an adequate candidate for transplant
- Radiology reports including:
  - Chest X-ray
  - Chest CT scan
- Colonoscopy report if > 50 years of age
- Cardiology procedures and pulmonary function reports:
  - Electrocardiogram (EKG)
  - Cardiac echocardiogram
  - Cardiac stress test
  - Cardiac catheterization
  - Pulmonary function tests (PFTs)
  - 6 minute walk study
- Laboratory reports

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**
The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Transplant Case Management Department. Please call 1-800-637-2066 ext. 3507708 or visit the Provider Portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.