Policy Statement

Lung transplantation may be considered medically necessary for carefully selected patients with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy (see Policy Guidelines).

A lobar lung transplant from a living or deceased donor may be considered medically necessary for carefully selected patients with end-stage pulmonary disease (see Policy Guidelines).

Lung or lobar lung retransplantation after a failed lung or lobar lung transplant may be considered medically necessary in patients who meet criteria for lung transplantation.

Lung or lobar lung transplantation is considered investigational in all other situations.

Policy Guidelines

Contraindications
Potential contraindications for lung transplant are subject to the judgment of the transplant center include the following:

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

Policy specific:

- Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function*; or
- Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria

* Some patients may be candidates for combined heart and lung transplantation (See Blue Shield of California Medical Policy: Heart/Lung Transplant).

Patients must meet United Network for Organ Sharing (UNOS) guidelines for a Lung Allocation Score greater than zero.

Lung-Specific Guidelines
Bilateral lung transplantation is typically required when chronic lung infection and disease is present (i.e., associated with cystic fibrosis and bronchiectasis). Some, but not all, cases of pulmonary hypertension will require bilateral lung transplantation.

Bronchiolitis obliterans is associated with chronic lung transplant rejection, and thus may be the etiology of a request for lung retransplantation.
Coding
Etiologies of end-stage lung disease include, but are not limited to, any conditions listed in Table PG1.

<table>
<thead>
<tr>
<th>Conditions</th>
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<tr>
<td>Bilateral bronchiectasis</td>
<td>J47.0–J47.1; Q33.4 for congenital bronchiectasis</td>
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<td>Primary pulmonary hypertension</td>
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<td>Cystic fibrosis (both lungs to be transplanted)</td>
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<td>Recurrent pulmonary embolism</td>
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<td>Eisenmenger syndrome</td>
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Description
A lung transplant consists of replacing all or part of diseased lungs with healthy lung(s) or lobes. Transplantation is an option for patients with end-stage lung disease.

Related Policies
- Heart/Lung Transplant
- Outpatient Pulmonary Rehabilitation

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
The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Pancreas transplants are included in these regulations.
Rationale

Background

End-Stage Lung Disease

End-stage lung disease may be the consequence of a number of different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, α1-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension.

Treatment

Before consideration for transplant, patients should be receiving maximal medical therapy, including oxygen supplementation, or surgical options, such as lung-volume reduction surgery for chronic obstructive pulmonary disease. Lung or lobar lung transplantation is an option for patients with end-stage lung disease despite these measures.

A lung transplant refers to single-lung or double-lung replacement. In a single-lung transplant, only 1 lung from a deceased donor is provided to the recipient. In a double-lung transplant, both the recipient's lungs are removed and replaced by the donor's lungs. In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions, and transplanted. Donors for lobar transplant have primarily been living-related donors, with 1 lobe obtained from each of 2 donors (generally friends or family members) in cases for which bilateral transplantation is required. There are also cases of cadaver lobe transplants.

Since 2005, potential recipients have been ranked according to the Lung Allocation Score. Patients 12 years of age and older receive a score between 1 and 100 based on predicted survival after transplantation reduced by predicted survival on the waiting list; the Lung Allocation Score takes into consideration the patient's disease and clinical parameters. In 2010, a simple priority system was implemented for children younger than age 12 years. Under this system, children younger than 12 years with respiratory lung failure and/or pulmonary hypertension who meet criteria are considered “priority 1” and all other candidates in the age group are considered “priority 2”. A lung review board has the authority to adjust scores on appeal for adults and children.

Literature Review

Assessment of efficacy for therapeutic intervention involves a determination of whether the 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.

Lung Transplantation

The Registry of the International Society for Heart and Lung Transplantation contains data from 49,453 adult recipients who received lung transplantation (including lung retransplantation) through June 30, 2015, at 134 transplant centers. A total of 55,795 lung transplants were performed, of which 53,522 (95.9%) were primary transplants and 2273 (4.1%) were retransplants. The overall median survival of patients who underwent lung transplantation was 5.8 years. Estimated unadjusted survival rates were 89% at 3 months, 80% at 1 year, 65% at 5 years, and 32% at 10 years. Patients who survived a year after primary transplantation had a median survival of 8.0 years. In the first 30 days after transplantation, the major reported causes of mortality were graft failure (24.5%) and non-cytomegalovirus (non-CMV) infections (19.1%) while non-CMV infections became the major cause of death for the remainder of the first year. Beyond the first year, the most common reported causes of mortality were obstructive...
bronchiolitis/bronchiolitis obliterans syndrome (OB/BOS), graft failure, and non-CMV infections. Beyond 10 years posttransplant, the major causes of mortality were OB/BOS (21.5%), non-CMV infection (16.5%), and nonlymphoma malignancy (13.7%).

The International Society for Heart and Lung Transplantation Registry contains a total of 2229 pediatric lung transplants performed through 2014. Most transplants (73%) were done in older children between the ages of 11 and 17 years. Median survival in children who underwent lung transplantation was 5.4 years, similar to survival in adults (mean survival, 5.7 years). However, median survival in children was lower (2.2 years) than in adults (5.6 years) for single-lung transplants.

In 2010, Thabut et al reported on a comparison between patients undergoing single- and double-lung transplantation for idiopathic pulmonary fibrosis. A retrospective review was conducted of 3327 patients with data in the United Network for Organ Sharing registry. More patients underwent single-lung transplant (64.5%) compared with double-lung transplant (35.5%). Median survival time was greater for the double-lung group at 5.2 years (95% confidence interval [CI], 4.3 to 6.7 years) than the single-lung group at 3.8 years (95% CI, 3.6 to 4.1 years; p<0.001). After adjusting for baseline differences, however, survival times did not differ statistically. The authors concluded that overall survival did not differ between the groups: single-lung transplants offered improved short-term survival but long-term harm, whereas double-lung transplant increased short-term harm but was associated with a long-term survival benefit. In 2014, Black et al reported on Lung Allocation Score (LAS) and single- vs double-lung transplant in 8778 patients (8050 had an LAS <75 vs 728 had an LAS ≥75). A significant decrease in survival was seen in single-lung transplant patients with a high LAS compared with double-lung transplant patients with a high LAS, even though operative morbidity was higher (p<0.001).

In 2010, Yusen et al reviewed the effect of the LAS on lung transplantation by comparing statistics for the period before and after its implementation in 2005. Other independent changes in clinical practice, which may affect outcomes over the same period of time, include variation in immunosuppressive regimens, an increased supply of donor lungs, changes in diagnostic mix, and increased consideration of older recipients. Deaths on the waiting list declined following implementation of the LAS system, from approximately 500 per 5000 patients to 300 per 5000 patients. However, it is expected that implementation of LAS affected patient characteristics of transplant applicants. One-year survival posttransplantation did not improve after implementation of the LAS system: patient survival data before and after are approximately 83%. Long-term survival data are not yet available for comparison. In 2014, Shafii et al reported on a retrospective evaluation of the LAS and mortality in 537 adults listed for lung transplantation and 426 who underwent primary lung transplantation between 2005 and 2010. Patients on the wait list who had a higher LAS had a higher mortality rate (p<0.001). In the highest quartile of LAS (range, 47-95), within 1 year of listing, there was a 75% mortality rate. Higher LAS was also associated with early posttransplant survival (p=0.05) but not late posttransplant survival (p=0.4). When other predictive factors of early mortality were accounted for, pretransplant LAS was not independently related to posttransplant mortality (p=0.12).

Section Summary: Lung Transplant
International registry data on a large number of patients receiving lung transplantation (>50,000) found relatively high patient survival rates (89% at 3 months, 80% at 1 year, 65% at 5 years, 32% at 10 years). In patients who survived a year, median survival was 8 years. After adjusting for potential confounding factors, survival did not differ significantly after single- or double-lung transplant.

Lobar Lung Transplantation
Date stated that, as of 2011, approximately 400 living-donor lobar lung transplants had been performed worldwide. Procedures in the United States decreased after 2005 due to changes in the lung allocation system. Date stated that size matching between donor and recipient is
important and that, to some extent, size mismatching (oversized or undersized grafts) can be overcome by adjusting surgical technique.

In 2017, Eberlein et al reported on a systematic review of studies on lobar lung transplantation from deceased donors.9 Reviewers identified 9 studies comparing outcomes after lobar lung or lung transplant, all of which were single-center retrospective cohort studies. Seven studies were conducted in Europe and one in Australia and one in North America. One-year survival reported in individual studies ranged from 50% to 100% after lobar lung transplant and from 72% to 88% after conventional lung transplant. In a pooled analysis of data from 8 studies, lobar lung transplant recipients (n=284) had a significantly higher risk of 1-year mortality than lung transplant recipients (n=2777) (relative risk [RR], 1.85; 95% CI, 1.52 to 2.25; p<0.001; I²=0%).

Several studies reported on lobar lung transplantation from living donors. For example, in 2005, Barr et al reported on living-donor lobar lung transplants in the United States.10 Ninety patients were adults and 43 were children. The primary indication for transplantation (86%) was cystic fibrosis. At the time of transplantation, 67% of patients were hospitalized, and 20% were ventilator dependent. Overall recipient actuarial survival rates at 1, 3, and 5 years were 70%, 54%, and 45%, respectively. There was no statistically significant difference in actuarial survival between adults and children who underwent transplantation. Moreover, survival rates were similar to the general population of lung transplant recipients. The authors also reported that rates of postoperative pulmonary function in patients surviving more than 3 months posttransplant were comparable with rates in cadaveric lung transplant recipients.

In 2015, Date et al reported on a retrospective study comparing 42 living-donor lobar lung transplants with 37 cadaveric lung transplants.11 Survival rates at 1 and 3 years did not differ significantly between groups (89.7 and 86.1% vs 88.3 and 83.1%, respectively, p=0.55), despite living-donor lobar lung transplant patients having poorer health status preoperatively. In 2012, a program in Japan reported on 14 critically ill patients (10 children and 4 adults) who had undergone single living-donor lobar lung transplants.12 Patients were followed for a mean 45 months. The 3-year survival rate was 70%, and the 5-year survival was 56%. Severe graft dysfunction occurred in 4 patients. Mean forced vital capacity was lower in patients experiencing severe graft dysfunction (54.5%) than in the other patients (66.5%). The authors stated that this suggested size mismatching in the patients with severe graft dysfunction.

In 2014, Slama et al reported on a comparison of outcomes in 138 cadaveric lobar lung transplants (for size discrepancies) with 778 patients who received cadaveric whole-lung transplants, 239 of whom had downsizing by wedge resection of the right middle lobe and/or the left lingula.13 Survival rates in the lobar lung transplant group at 1 and 5 years were 65.1% and 54.9% vs 84.8% and 65.1% in the whole-lung and downsized by wedge resection group (p<0.001). The lobar lung transplantation group experienced significantly inferior early postoperative outcomes, but in patients who were successfully discharged, survival rates were similar to standard lung transplantation (p=0.168).

**Section Summary: Lung Lobar Transplant**
There are fewer data on lung lobar transplants than on whole-lung transplants. The available data reported in case series has suggested reasonably similar survival outcomes, and lung lobar transplants may be the only option for patients unable to wait for a whole-lung. A 2017 systematic review found 1-year survival rates in the available published studies ranging from 50% to 100%.

**Lung or Lobar Retransplantation**
Registry data and case series reports have demonstrated favorable outcomes with lung retransplantation in certain populations, such as in patients who meet criteria for initial lung transplantation.14-16
The Organ Procurement and Transplantation Network has reported data on lung transplants performed between 2008 and 2015. Patient survival rates after repeat transplants were lower than primary transplants, but a substantial number of patients survived. For example, 1-year patient survival was 87.9% (95% CI, 87.2% to 88.7%) after a primary lung transplant and 76% (95% CI, 70.9% to 80.2%) after a repeat transplant. Five-year patient survival rates were 55.9% (54.7% to 57.2%) after a primary lung transplant and 33.8% (28.5 to 39.1%) after repeat transplant.

The International Society for Heart and Lung Transplantation Registry contains data on 2273 retransplantation patients performed through June 2015 (4.4% of lung transplantations). The major causes of death in the first 30 days after retransplantation were graft failure and non-CMV infection, followed by multiorgan failure, cardiovascular causes, and technical factors related to the transplant procedure. Beyond the first year, the most common reported causes of mortality were OB/BOS, graft failure, and non-CMV infections.

**Section Summary: Lung or Lobar Retransplant**

Data from registries and case series have found favorable outcomes with lung retransplantation in patients who meet criteria for initial lung transplantation. Given the exceedingly poor survival without retransplantation of patients who have exhausted other treatments, evidence of a moderate level of posttransplant survival is sufficient in this patient population.

**Potential Contraindications (Applies to all Indications above)**

**Malignancy**

Malignancies are common after lung transplantation, with 21% and 40% of patients reporting 1 or more malignancies at 5 and 10 years posttransplantation, respectively. Skin cancer occurred most frequently, and lymphoproliferative disorders were the malignancies most associated with morbidity posttransplantation.

A 2012 study reported on outcomes in patients with lung cancer who were lung transplant recipients. Ahmad et al identified 29 individuals in the United Network for Organ Sharing database who underwent lung transplantation for advanced bronchoalveolar carcinoma. These patients represented 0.13% of the 21,553 lung transplantations during the study period. Bronchoalveolar carcinoma and general lung transplant recipients had similar survival rates: the 30-day mortality rate was 7% vs 10% (p=0.44) and the 5-year survival rate was 50% vs 57% (p=0.66).

**HIV**

Current Organ Procurement and Transplantation Network policy on Identification of Transmissible Diseases states: “OPTN [Organ Procurement and Transplantation Network] permits HIV test-positive individuals as organ candidates if permitted by the transplant hospital.”

In 2006, the British HIV Association and the British Transplantation Society published guidelines on kidney transplantation in patients with HIV disease. These criteria may be extrapolated to other organs:

- CD4 count greater than 200 cells/mL for at least 6 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- Demonstrable adherence and a stable highly active antiretroviral therapy regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after highly active antiretroviral therapy

**Other Infections**

Infection with *Burkholderia cenocepacia* is associated with increased mortality in some transplant centers, a factor that may be taken into account when evaluating overall risk for transplant survival. Two articles published in 2008 evaluated the impact of infection with various species of *Burkholderia* on outcomes for lung transplantation for cystic fibrosis. In a study by Murray et al, multivariate Cox survival models assessing hazard ratios were applied to 1026 lung
transplant candidates and 528 transplant recipients. Of the transplant recipients, 88 were infected with Burkholderia. Among transplant recipients infected with B. cenocepacia, only those infected with nonepidemic strains (n=11) had significantly greater posttransplant mortality than uninfected patients (hazard ratio, 2.52; 95% CI, 1.04 to 6.12; p=0.04). Transplant recipients infected with Burkholderia gladioli (n=14) also had significantly greater posttransplant mortality than uninfected patients (hazard ratio, 2.23; 95% CI, 1.05 to 4.74; p=0.04). When adjustments for specific species/strains were included, IAS of Burkholderia multivorans-infected transplant candidates were comparable with uninfected candidate scores, and scores for patients infected with nonepidemic B. cenocepacia or B. gladioli were lower. In a smaller study of 22 patients colonized with Burkholderia cepacia complex who underwent lung transplantation in 2 French centers, the risk of death by univariate analysis was significantly higher for the 8 patients infected with B. cenocepacia than for the other 14 colonized patients (11 of whom had B. multivorans).

A 2016 analysis of international registry data found that non-CMV infection is a major cause of mortality within 30 days of a lung transplant in adults. A total of 655 (19%) of 3424 deaths after transplants between 1990 and 2015 were due to non-CMV infection. Only 3 (0.1%) of the deaths were due to CMV infection.

Summary of Evidence
For individuals who have end-stage pulmonary disease who receive lung transplantation, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. International registry data on a large number of patients receiving lung transplantation (>50,000) found relatively high patient survival rates, especially among patients who survived the first year posttransplant. After adjusting for potential confounding factors, survival did not differ significantly after single- or double-lung transplant. Lung transplantation may be the only option for some patients with end-stage lung disease. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage pulmonary disease who receive lobar lung transplantation, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, change in disease status, and treatment-related mortality and morbidity. There are less data on lung lobar transplants than on whole-lung transplants, but several case series have reported reasonably similar survival outcomes between the procedures, and lung lobar transplants may be the only option for patients unable to wait for a whole-lung transplant. A 2017 systematic review found 1-year survival rates in the available published studies ranging from 50% to 100%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a prior lung or lobar transplant who meet criteria for a lung transplant who receive a lung or lobar lung retransplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, treatment-related mortality and morbidity. Data from registries and case series have found favorable outcomes with lung retransplantation in patients who meet criteria for initial lung transplantation. Given the exceedingly poor survival without retransplantation of patients who have exhausted other treatments, evidence of a moderate level of posttransplant survival is sufficient in this patient population. 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
In 2006, the International Society for Heart and Lung Transplantation published consensus-based guidelines on selection of lung transplant candidates. The guidelines stated that:

“Lung transplantation is now a generally accepted therapy for the management of a wide range of severe lung disorders, with evidence supporting quality of life and survival benefit
for lung transplant recipients. However, the number of donor organs available remains far fewer than the number of patients with end-stage lung disease who might potentially benefit from the procedure. It is of primary importance, therefore, to optimize the use of this resource, such that the selection of patients who receive a transplant represents those with realistic prospects of favorable long-term outcomes.

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

Medicare National Coverage
Lung transplantation is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare and Medicaid Services have stated that under certain limited cases, exceptions to the facility-related criteria may be warranted if there is justification and the facility ensures safety and efficacy objectives.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

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<td>Prognosis of Lung Transplant Candidates</td>
<td>100</td>
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<td>NCT00177918</td>
<td>Prospective Evaluations of Infectious Complication in Lung Transplant Recipients</td>
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NCT: national clinical trial.

References

**Documentation for Clinical Review**

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

- Referring physician history and physical
- 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:
  o Clinical history
  o Specific issues identified during the transplant evaluation
  o Consultation reports/letters (when applicable)
  o Correspondence from referring physicians (when applicable)
• 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
• Radiological reports including:
  o Chest x-ray (CXR)
  o Chest CT
• Colonoscopy report if > 50 years of age
• Cardiology procedures and respiratory function reports:
  o EKG
  o Cardiac echocardiogram, stress test, and cardiac catheterization (if needed)
  o Pulmonary function tests (PFTs)
  o 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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**ICD-10 Diagnosis**

All Diagnoses

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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.