SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

All organ transplantations are approved on a case by case basis subject to Plan review.

Organ Procurement

Organ procurement for transplantation is defined as those medical services necessary for the removal, preservation, transportation, and storage of an organ, marrow, or stem cells. Organ acquisition charges are considered part of organ procurement. Organ procurement is subject to contract benefit and limitations.

The following organ transplants are addressed in this policy: (see below for organ specific medical necessity criteria)

- Heart transplantation
<table>
<thead>
<tr>
<th>MEDICAL POLICY</th>
<th>Organ Transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Heart/lung transplantation</td>
</tr>
<tr>
<td></td>
<td>Single/double lung transplantation</td>
</tr>
<tr>
<td></td>
<td>Liver transplantation</td>
</tr>
<tr>
<td></td>
<td>Kidney transplantation</td>
</tr>
<tr>
<td></td>
<td>Simultaneous pancreas and kidney transplantation</td>
</tr>
<tr>
<td></td>
<td>Pancreas after kidney transplants</td>
</tr>
<tr>
<td></td>
<td>Intestinal transplantation (alone, combined liver-intestinal, and multivesicular [stomach, duodenum, pancreas, liver, and intestine])</td>
</tr>
<tr>
<td></td>
<td>Corneal transplantation (no prior authorization required)</td>
</tr>
</tbody>
</table>

**General Transplant Candidacy Criteria**

I. Organ transplantation may be considered **medically necessary and covered** when the following criteria are met:

   A. Medical history and request for authorization must be submitted to the Plan;
   B. The Plan may request an additional medical assessment as well as a conference session with the patient and family to discuss benefits, as well as psycho-social support systems available to maintain life-long post-transplant care for maximum graft survival;
   C. A pattern of demonstrated patient noncompliance which would place a transplanted organ at serious risk of failure is a contraindication for transplant;
   D. A BMI of greater than 35.0 is a relative contraindication for transplant. Candidates with a BMI between 35.1 and 39.9 may be considered on an individual basis if:

      1. The member’s condition is eminently life threatening without transplant, or
      2. Candidate has no other health conditions other than their end-stage organ disease and no cardiac risk factors including:
         a. high cholesterol
         b. elevated triglycerides
         c. hypertension, type 2 diabetes
         d. other factors revealed in cardiac testing)
   3. A BMI of 40.0 or greater is an absolute contraindication to transplant.

   E. Smoking/tobacco use, is contraindicated for transplant patients. Members who smoke currently need to demonstrate their willingness and ability to stop smoking before transplant related services. An evaluation, will be authorized and reimbursed by Providence Health Plan and include the following:

      1. Several random clean screens for nicotine and cotinine, arranged through the member’s physician, and span at least a current 30 day period, will satisfy this requirement. Random screens may be required periodically throughout the evaluation period and time on the waiting list for continued prior authorization of transplant related services. If a candidate has recently stopped smoking, a random screen may be required to confirm continued abstinence before transplant services are approved.
F. Successful documentation of treatment and/or abstinence from alcohol or substance use for a minimum of six (6) months. Evaluation for transplant may begin if member is actively participating in a treatment program.

Living Donor Criteria

II. Organ transplant donors must meet all of the following criteria:

   A. No medical or psychological contraindications; and
   B. Non-smoker; and
   C. BMI equal to or less than 35.

General Transplant Facility Criteria

III. Organ transplantation may be performed at facilities which meet the following criteria:

   A. The transplant facility meets any one of the following criteria:
      1. Is a Center of Excellence (COE); or
      2. A Providence Health Plan (PHP) approved facility (PHP has negotiated a contract, either directly or through a participating transplant network); or
      3. An UNOS/Medicare approved facility.

   B. The transplant will be performed in-plan at a facility identified in criterion II.A., unless any of the following are met:
      1. Services are not available at an applicable facility (criterion II.A.) and/or in-plan; or
      2. When documented better outcomes can be provided at an alternative setting; or
      3. Extenuating circumstances (commercial member only) - "if specialist and member request and support transplant at non-approved facility - member must sign letter of understanding." Extenuating circumstances do not apply to Medicare or OHP members.

   C. The transplant program must demonstrate a commitment to excellence.
   D. For Medicare members, the facility must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

Organ Specific Criteria

IV. Organ transplants may be considered medically necessary and covered when they meet selection criteria for the requested organ at the transplant facility they are referred to. All organ transplants must be in accordance with standard medical practice and may be approved subject to plan review.

   A. Heart Transplant
Heart transplant may be covered in members with end-stage myocardial failure (NYHA - Class 4 failures or rapidly progressive [over months] NYHA Class III) i.e., patients with poor prognosis who:

1. Failed medical management; and
2. Have no other end-stage disease or severe disease process that would compromise the success of the heart transplant. Examples may include but are not limited to:
   a. Cardiomyopathy
   b. Coronary artery disease

NOTE: See Providence Health Plan (PHP) medical policy: Cardiac: Ventricular Assist Devices (VAD/LVAD) and Artificial Heart (Biventricular) Devices for criteria regarding artificial hearts and related devices. Animal to human transplants are not covered.

B. Heart/Lung Transplant

A heart/lung transplant may be covered in members with end-stage pulmonary and pulmonary vascular disease with associated heart failure and where no other form of medical/surgical therapy offers the prospect of extended survival. Examples of end-stage conditions may include, but are not limited to:

1. Primary pulmonary hypertension
2. Eisenmenger's Syndrome (ASD, VAS, PA, TRUNCUS, other complex anomalies)
3. Pulmonary hypertension secondary to thromboembolic disease
4. Cardiomyopathy with pulmonary hypertension
5. Congenital abnormalities such as univentricular heart with pulmonary atresia
6. Cystic fibrosis with severe irreversible end-stage pulmonary disease

C. Single/Double Lung Transplant

A single or double lung transplant may be covered when the following criteria are met:

1. Poor prognosis without a transplant as a result of poor pulmonary functional status; and
2. All alternative, medically accepted treatments, comparable to transplant, must have been tried and/or considered.
3. For pediatric patients, requests for transplant services for pediatric members suffering from early cardio-pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve outcome. Examples may include, but are not limited to the following:
   a. Fibrotic lung disease
b. Pulmonary hypertension with reversible RV function  
c. Alpha 1-Antitrypsin deficiency  
d. Emphysema  

D. Liver Transplant  
Liver transplantation may be covered in members with end-stage irreversible liver disease when no medical or surgical alternatives to transplantation are available. Examples may include but are not limited to:  
1. Primary biliary cirrhosis;  
2. Alcoholic cirrhosis (documentation of successful treatment and/or substance use for a minimum of six (6) months) and agreement for ongoing random drug screens;  
3. Post-hepatic cirrhosis, hepatitis B surface antigen negative;  
4. Primary sclerosing cholangitis;  
5. Hepatocellular carcinoma (HCC) when Milan Criteria is met. Milan Criteria = solitary tumor ≤ 5 cm or ≤ 3 lesions none > 3 cm.  

E. Kidney Transplant  
Kidney transplantation may be covered in members who have documented end-stage renal disease. For patients not yet on dialysis, glomerular filtration rate must be <20, consistent with UNOS listing criteria. End-stage renal disease is that stage of kidney impairment that appears irreversible and permanent.  

F. Simultaneous Pancreas and Kidney Transplantation and Pancreas after Kidney Transplant (PAK)  
Simultaneous pancreas and kidney transplantation and pancreas after kidney transplant (PAK) may be covered in members who meet the following criteria:  
1. Insulin dependent type I diabetes (confirmed through c-peptide test); and  
2. End-stage renal failure or non-uremic renal dysfunction.  

G. Intestinal Transplant  
An intestinal transplant may be covered in members when the following criteria are met:  
1. Coverage is limited to patients who have failed total parenteral nutrition (TPN).  
2. For Medicare members, only centers performing at least 10 intestinal transplants a year and have a 65%, a 1 year patient survival, will be eligible per year Medicare coverage.
3. For patients who have failed TPN due to liver failure, thrombosis, or frequency of infection and dehydration, intestinal transplantation is indicated in the following clinical situations:

   a. Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding, or hepatic fibrosis/cirrhosis.

   b. Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, superior vena cava syndrome, or chronic venous insufficiency.

   c. Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or acute Respiratory Distress Syndrome are considered indicators of TPN failure.

   d. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructible gastrointestinal tract, the loss of the gastrointestinal and pancreaticobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly the kidneys and central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

H. Corneal Transplant

Corneal transplant may be covered corneal conditions which obstruct vision, including but not limited to external eye diseases which causes damage to the cornea such as:

1. Trauma; or
2. Infection; or
3. Scarring.

Corneal transplantation is not approved if there is another vision problem or disease process within the eye that would prevent a successful transplantation.

Other Transplants and Related Services

V. Peripheral stem cell harvest and/or storage is considered not medically necessary and not covered unless the service is in conjunction with an imminently scheduled autologous transplant which has been prior authorized by Providence Health Plans.
VI. Medicare guidelines for coverage of stem cell/bone marrow transplant related services will be followed for all members where Providence Health Plans does not list specific criteria for coverage, subject to the members plan benefit.

DESCRIPTION

Transplantation is the grafting of living tissue from a part of one individual, the donor, to another individual, the recipient. The tissue or organ to be transplanted may be obtained from a living or non-living donor.

Organ procurement for transplantation is defined as those medical services necessary for the removal, preservation, transportation, and storage of an organ, marrow, or stem cells. Organ acquisition charges are considered part of organ procurement.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES