

MEDICAL POLICY	Organ Transplantation (All Lines of Business Except Medicare)	
Effective Date: 2/1/2021  <div style="text-align: right;">2/1/2021</div>	Section: SUR	Policy No: 294
	Medical Policy Committee Approved Date: 4/01; 6/02; 7/03;7/04; 7/06; 7/07; 7/09; 7/11; 5/13; 8/14; 9/15; 12/16; 2/18; 2/19; 2/2020; 5/2020; 1/2021	
Medical Officer	Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

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 except Medicare

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.

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
 - History
 - Physical examination
 - Treatment plan
 - Psychosocial history
 - Diagnostic testing
 - Documentation of treatment and/or abstinence from alcohol or substance use for a minimum of six (6) months

Note: The Plan may request an additional medical assessment as well as a conference session with the patient and family to discuss benefits and psycho-social support systems available to maintain life-long post-transplant care.

POLICY CRITERIA

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

- [Heart transplantation](#)
- [Heart/lung transplantation](#)
- [Single/double lung transplantation](#)
- [Liver transplantation](#)
- [Kidney transplantation](#)
- [Simultaneous pancreas and kidney transplantation/Pancreas after kidney transplants](#)
- [Intestinal transplantation](#) (alone, combined liver-intestinal, and multivesicular [stomach, duodenum, pancreas, liver, and intestine])
- [Corneal transplantation](#)

General Transplant Candidacy Criteria

- I. Organ transplantation may be considered **medically necessary and covered** when the following criteria are met (A.-D.):
 - A. Member meets **at least one** of the following (1. or 2.) criteria:
 1. BMI of lesser or equal to 35.0 **or**
 2. BMI between 35.1 and 39.9 may be considered on an individual basis if:
 - a. The member's condition is eminently life threatening without transplant; **or**
 - b. No other health conditions other than their end-stage organ disease and no cardiac risk factors including:
 - i. high cholesterol; **or**
 - ii. elevated triglycerides; **or**
 - iii. hypertension, type 2 diabetes; **or**
 - iv. other factors revealed in cardiac testing; **and**
 - B. Member meets **at least one** of the following (1. or 2.) criteria:
 1. Is a non-smoker; **or**
 2. Current and/or recent smokers (i.e. within the past year) have ceased smoking for at least 4 weeks prior to transplant and are willing to refrain from smoking after surgery for 3 months. (**Note:** To ensure compliance, laboratory testing will be required at Medical Director discretion); **and**
 - C. If applicable, 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; **and**
 - D. Organ transplantation must be performed at an approved transplant facility (see [Policy Guidelines](#) for approved transplant facilities).

- II. Organ transplantation is considered **not medically necessary and not covered** when criterion I.(A.-D.) is not met.

Organ Specific Criteria

Heart Transplant

- III. Heart transplant may be considered **medically necessary and covered** in members with end-stage myocardial failure (NYHA - Class 4 failures or rapidly progressive [over months] NYHA Class III) who meet **all** of the following criteria (A.-C.):
- A. Criteria I.A.-D. above is met; **and**
 - B. Failed medical management; **and**
 - C. 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:
 - 1. Cardiomyopathy; **or**
 - 2. 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.

Heart/Lung Transplant

- IV. A heart/lung transplant may be **medically necessary and covered** when **all** the following criteria are met (A.-C.):
- A. Criteria I.A.-D. above is met; **and**
 - B. Member has end-stage pulmonary and pulmonary vascular disease with associated heart failure; **and**
 - C. 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; **or**
 - 2. Eisenmenger's Syndrome (ASD, VAS, PA, TRUNCUS, other complex anomalies) ;
or
 - 3. Pulmonary hypertension secondary to thromboembolic disease; **or**
 - 4. Cardiomyopathy with pulmonary hypertension; **or**
 - 5. Congenital abnormalities such as univentricular heart with pulmonary atresia; **or**
 - 6. Cystic fibrosis with severe irreversible end-stage pulmonary disease.

Single/Double Lung Transplant

- V. A single or double lung transplant may be **medically necessary and covered** when **all** of the following criteria are met (A.-D.):
- A. Criteria I.A.-D. above is met; **and**

- B. Poor prognosis is excepted without a transplant as a result of insufficient pulmonary functional status; **and**
- C. All alternative, medically accepted treatments, comparable to transplant, have been tried and/or considered; **and**
- D. 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:
 - 1. Fibrotic lung disease; **or**
 - 2. Pulmonary hypertension with reversible RV function; **or**
 - 3. Alpha 1-Antitrypsin deficiency; **or**
 - 4. Emphysema; **or**
 - 5. Cystic Fibrosis; **or**
 - 6. Interstitial pulmonary disease; **or**
 - 7. Idiopathic pulmonary hypertension.

Liver Transplant

- VI. Liver transplantation may be **medically necessary and covered** when **all** of the following criteria are met (A.-C.):
 - A. Criteria I.A.-D. above is met; **and**
 - B. Member has end-stage irreversible liver disease; **and**
 - C. No medical or surgical alternatives to transplantation are available. Examples may include but are not limited to:
 - 1. Primary biliary cirrhosis; **or**
 - 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; **or**
 - 3. Post-hepatic cirrhosis, hepatitis B surface antigen negative; **or**
 - 4. Primary sclerosing cholangitis; **or**
 - 5. Hepatocellular carcinoma (HCC) when Milan Criteria is met. Milan Criteria = solitary tumor ≤ 5 cm or ≤ 3 lesions none > 3 cm; **or**
 - 6. Biliary atresia.

Kidney Transplant

- VII. Kidney transplantation may be **medically necessary and covered** when **all** of the following criteria are met (A.-C.):
 - A. Criteria I.A.-D. above is met; **and**
 - B. Member has documented end-stage renal disease; **and**
 - C. For patients not yet on dialysis, glomerular filtration rate must be <20 , consistent with UNOS listing criteria.

Simultaneous Pancreas and Kidney Transplantation and Pancreas after Kidney Transplant (PAK)

- VIII. Simultaneous pancreas and kidney transplantation and pancreas after kidney transplant (PAK) may be **medically necessary and covered** when **all** the following criteria are met (A.-C.):
- A. Criteria I.A.-D. above is met; **and**
 - B. Member has insulin dependent type I diabetes (confirmed through c-peptide test); **and**
 - C. Member has end-stage renal failure or non-uremic renal dysfunction.

Intestinal Transplant

- IX. An intestinal transplant may be **medically necessary and covered** when **all** of the following criteria are met (A.-C.):
- A. Criteria I.A.-D. above is met; **and**
 - B. Member has failed total parenteral nutrition (TPN) due to liver failure, thrombosis, or frequency of infection and dehydration; **and**
 - C. **At least one** of the following (1.-4.) clinical situations is met:
 - 1. Impending or overt liver failure due to TPN induced liver injury; **or**
 - 2. Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins; **or**
 - 3. Frequent episodes (two or more) of line infection and sepsis; **or**
 - 4. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

Corneal Transplant

- X. Corneal transplant may be **medically necessary and covered** for when **all** of the following criteria are met (A.-C.):
- A. Criteria I.A.-D. above is met; **and**
 - B. Member has an indication which obstructs 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; **and**
 - C. There is no other vision problem or disease process within the eye that would prevent a successful transplantation.

POLICY GUIDELINES

Approved Transplant Facilities

- Center of Excellence (COE)/Blue Distinction Center for Transplants (BDCT);
- A Providence Health Plan (PHP) approved facility (PHP has negotiated a contract, either directly or through a participating transplant network)

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral
32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy
47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)

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47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (ie, left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII])
47145	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe (segments I, V through VIII))
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each

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50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor
0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed
0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field
0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour (List separately in addition to code for primary procedure)

DESCRIPTION

Transplantation

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.¹

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.²

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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Cardiac: Ventricular Assist Devices (VAD/LVAD)
- Artificial Heart (Biventricular) Devices for criteria regarding artificial hearts and related devices.

REFERENCES

1. UNOS. Organ transplant. <https://unos.org/transplant/>. Accessed 11/18/2020.
2. Organ Procurement and Transplantation Network. Organ procurement and transplantation network policies. Effective 9/10/2020. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Accessed 11/18/2020.