
Organ Transplantation

MEDICAL POLICY NUMBER: 159

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| Effective Date: 4/1/2024 | COVERAGE CRITERIA | 2 |
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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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Solid Organ Transplants: Lines 83,99,162,239,240,241,263,264,307,310,563

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE 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** 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) (see [Policy Guidelines](#) for definition of smoker) 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** when criterion I.(A.-D.) is not met.

Organ Specific Criteria

Heart Transplant

- III. Heart transplant may be considered **medically necessary** 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.

Heart/Lung Transplant

- IV. A heart/lung transplant may be **medically necessary** 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** when **all** of the following criteria are met (A.-D.):
- A. Criteria I.A.-D. above is met; **and**
 - B. Poor prognosis is expected 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** 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. Alcohol-associated cirrhosis without acute alcohol-associated hepatitis (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 \leq 5 cm or \leq 3 lesions none $>$ 3 cm; **or**
 - 6. Biliary atresia.

Kidney Transplant

- VII. Kidney transplantation may be **medically necessary** 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** when **all** the following criteria are met (A.-C.):

- A. Criteria I.A.-D. above is met; **and**
- B. Member has insulin-dependent 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** 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** 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

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

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)

Definition of smoker: Includes smoking cigarettes, cigars, and pipe smoking of tobacco.

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.

BACKGROUND

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

BILLING GUIDELINES AND CODING

HCPCS codes S2053, S2054, S2055, and S2152 are not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy (*HCPCS S-Codes and H-Codes*, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for this service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

| CODES* | | |
|--------|-------|---|
| CPT | | 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 |
| | 0494T | |
| | | 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 |
| | 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; each additional hour (List separately in addition to code for primary procedure) |
| | 0496T | |
| | 32850 | Donor pneumonectomy(s) (including cold preservation), from cadaver donor |
| | 32851 | Lung transplant, single; without cardiopulmonary bypass |
| | 32852 | Lung transplant, single; with cardiopulmonary bypass |
| | | Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass |
| | 32853 | |
| | | Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass |
| | 32854 | |
| | | 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 |
| | 32855 | |
| | | Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues |
| | 32856 | |

| | | |
|--|-------|--|
| | | 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 |
| | 44132 | Donor enterectomy, (including cold preservation) open; from cadaver donor |
| | 44133 | Donor enterectomy (including cold preservation), open; partial, from living donor |
| | 44135 | Intestinal allotransplantation; from cadaver donor |
| | 44136 | Intestinal allotransplantation; from living donor |
| | 44715 | Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein |
| | 44720 | Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each |
| | 44721 | Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each |
| | 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) |
| | 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 |
| 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 |
| 50380 | | Transplant Renal Autograft |

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|--------------|-------|---|
| | 50547 | Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor |
| | 65710 | Keratoplasty (corneal transplant); anterior lamellar |
| | 65730 | Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia) |
| | 65750 | Keratoplasty (corneal transplant); penetrating (in aphakia) |
| | 65755 | Keratoplasty (corneal transplant); penetrating (in pseudophakia) |
| | 65756 | Keratoplasty (corneal transplant); endothelial |
| | 65757 | Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure) |
| | 65767 | Epikeratoplasty |
| HCPCS | V2785 | Processing, preserving and transporting corneal tissue |

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. UNOS. Organ transplant. <https://unos.org/transplant/>. Accessed 12/22/2023.
2. Organ Procurement and Transplantation Network. Organ procurement and transplantation network policies. Effective 10/27/2022. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf. Accessed 12/22/2023.

POLICY REVISION HISTORY

| DATE | REVISION SUMMARY |
|--------|---|
| 2/2023 | Converted to new policy template. |
| 8/2023 | Liberalized criterion VIII.B. |
| 2/2024 | Annual update. No change to criteria or coding. |
| 4/2024 | Interim update. Added code. |