Medical Coverage Policy

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Transplantation Donor Charges

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses transplantation donor charges/expenses.

Coverage Policy

Transplantation donor expenses are covered under the transplantation recipient’s benefit plan when ALL of the following criteria are met:

- The recipient of the transplantation meets ALL of the following criteria:
  - is eligible for coverage under a Cigna health benefit plan
  - has a condition for which the proposed transplantation is considered medically necessary
  - meets the coverage criteria for transplantation
- Eligible donor meets OPTN/UNOS (Organ Procurement and Transplantation Network/United Network for Organ Sharing) donor evaluation and guideline criteria for the specific transplantation being performed (e.g., living kidney transplant, living liver transplantation).
- The organ to be donated is appropriate for the proposed transplant.
- For a bone-marrow, peripheral-blood or umbilical-cord blood stem-cell transplant, there is an identified, appropriate, allogeneic match between the donor and the recipient.
- The charges are not covered by the donor’s benefit plan.

The following are considered medically necessary or otherwise covered when the transplantation recipient is eligible for coverage for transplantation service under a Cigna health benefit plan:

- deceased (i.e., cadaveric) donor: organ/tissue procurement, including preservation, storage and transportation
- living donor:
  - solid organs: testing for related and unrelated donors as approved by Cigna
  - bone marrow, stem cell or umbilical cord blood: related-donor testing and unrelated-donor search fees and procurement if billed through the National Marrow Donor Program or other recognized marrow registry
  - prediagnostic testing expenses
  - hospital and surgical expenses for removal of the donor tissue/organ, and all services provided during the inpatient admission
  - transportation of the donated tissue/organ
  - lodging, food and transportation to and from the transplantation site for donors receiving services from a transplantation facility, for the donation procedure, for recipients who have this benefit
  - pursuant to standard contract terms, coverage is limited to 30 days of follow-up care after date of donation for transplant-related complications, if not otherwise covered by donor’s own health benefit plan

Transplantation donor expenses for non-human organ transplants are considered experimental, investigational or unproven.

**General Background**

According to the U.S. Government Information on Organ Donation and Transplantation:

- 113,000+ is the number of men, women and children on the national transplant waiting list as of July 2019.
- 36,528 transplants were performed in 2018
- 20 people die each day waiting for a transplant
- 95% of U.S. adults support organ donation but only 58% are actually signed up as donors
- every 10 minutes another person is added to the waiting list
- only 3 in 1,000 people die in a way that allows for organ donation
- In 2018, there was a total of 17,553 donors; 10,722 were deceased donors and 6,831 were living donors. 35% of deceased donors in 2018 were over the age of 50. 61% of deceased donors in 2018 were male, 39% female.

Solid-organ transplantation is the treatment of last resort for patients with end-stage organ disease. Many types of organs can be successfully transplanted, including the heart, lungs, kidney, small bowel, pancreas and liver. Solid-organ transplantation may be from a living or deceased (i.e., cadaveric) donor. In a solid-organ transplant, a healthy donor organ replaces the recipient’s diseased organ.

Marrow or blood cell transplantation is a life-saving treatment for numerous blood diseases, such as leukemia and lymphoma. This type of transplantation replaces the individual’s unhealthy blood cells with healthy blood-forming cells from a donor. Three sources of blood-forming cells include marrow, blood-forming cells collected from the blood (called peripheral-blood stem-cell donation [PBSC]) and umbilical cord blood. Transplantation involving the use of the individual’s own cells is referred to as an autologous transplant. During this procedure,
cells are collected from the patient’s blood or, less frequently, marrow, and stored for a transplant. Using transplantation cells from a family member, an unrelated donor, or cord blood is referred to as an allogeneic transplant. Syngeneic transplantation is a transplantation method using cells from an identical twin.

Xenotransplantation refers to any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source; or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. Interest in xenotransplantation is the result of various factors, including an insufficient number of available human organs for transplantation, advancements in genetics, and other scientific advances. However, several barriers exist to xenotransplantation and include severe rejection responses, difficulty controlling immune responses, and infectious disease issues. The U.S. Food and Drug Administration (FDA) note these Criteria for Xenotransplantation Patient Selection: “Due to the potentially serious public health risks of possible zoonotic infections, you should limit xenotransplantation to patients with serious or life-threatening diseases for whom adequately safe and effective alternative therapies are not available, except when very high assurance of safety can be demonstrated. You should limit candidates to those patients who have potential for a clinically significant improvement with increased quality of life, following the procedure. You should also consider the patient’s ability to comply with public health measures as stated in the protocol, including long-term monitoring” (FDA, 2016). Xenotransplantation is regulated by the U.S. Food and Drug Administration, nonetheless, significant concerns have been raised regarding safety, and further study is needed to demonstrate safety and impact on health outcomes.

Solid-Organ Transplantation

Deceased Donors: The ideal (deceased) organ-donor candidate is an individual who has suffered a fatal injury to the brain (with impending or actual brain death), yet has intact cardiovascular function. Potential donors must meet the following criteria:

- brain death
- free of infection
- no history of carcinoma, with the exception of low-grade skin or brain tumors
- free of severe systemic disease
- relatively normal organ function
- hemodynamically salvageable

Once a deceased donor has been identified, an organ procurement organization (OPO) coordinator will begin the process of evaluating the suitability of the donor. A complete medical and social history will be conducted to determine that the donor meets the above criteria.

Living Donors: Living-donor organ donation has increased due to the limited availability of deceased donor organs. Living-donor transplants are used in liver, kidney and lung transplantation, and investigations of living-donor pancreas and intestine donation are being conducted.

Kidney Disease: Improving Global Outcomes (KDIGO) published a Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors (Lentine, et al., 2017). OPTN/UNOS has issued various other guidelines, including but not limited to those for Living Donation (OPTN, 2019). Informed consent must be obtained from living donors. The donor’s signature on a document must clearly confirm that the donor:

- is willing to donate
- is free from inducement and coercion and
- has been informed that he or she may decline to donate at any time

Living donors must be provided an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential. Living donors must be provided an Independent Living Donor Advocate (ILDA) to assist the donor during the consent process, with instruction about all phases of the living donation process, which include:

- consent
- medical and psychosocial evaluations
• pre and post-operative care
• required post-operative follow up

Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine or lung donors. For any living kidney donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each potential living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor.

The ILDA must:
1. Function independently from the transplant candidate’s team.
2. Advocate for the rights of the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital’s protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor’s decision about whether to donate. Document that each requirement has been met.
4. Review and document whether the living donor has received information on numerous issues (OPTN/UNOS Living Donation Policy 14; 9/24/2019).

Bone-Marrow, Peripheral-Blood and Umbilical-Cord Blood Stem-Cell Donors
Stem cells are a type of cell that can grow into other types of cells, including red blood cells, white blood cells, and platelets. They are generated in the bone marrow and found in the bone-marrow, blood-forming cells collected from the blood (called peripheral-blood stem-cell donation [PBSC]) and umbilical cord blood. Donated stem cells are used to help the recipient produce components of his or her blood compromised by disease or by the treatment of certain diseases, such as cancer.

In general, bone-marrow, peripheral-blood and umbilical-cord blood stem-cell donors must meet the following medical criteria (National Marrow Donor Program, 2018):

- between the ages of 18 and 60. Ages of 18 and 44 are preferred because younger donors produce more and higher-quality cells than older donors.
- in good health
- tissue match to recipient
- body mass index (BMI) of 40 or less

Bone-Marrow Donor: Bone-marrow donation involves a minor surgical procedure, which is performed under local or general anesthetic. Four to eight small incisions are made in the pelvic area, and bone marrow is extracted with a surgical needle. The process takes 45–90 minutes. The donor may initially have soreness at the donation sites, but a full recovery generally occurs within a few days. The donor’s system will completely replace the extracted marrow within a few weeks, since marrow continuously regenerates itself.

Peripheral-Blood Stem-Cell (PBSC) Donor: PBSC donation requires the donor to receive medication, such as growth factor (e.g., filgrastim), for several days to increase the number of stem cells released from the bone marrow into the bloodstream. Donors may experience bone pain, muscle pain, nausea, insomnia and fatigue from the medication. The stem cells are collected by apheresis. In apheresis, blood is drawn through a needle from one arm, run through an apheresis machine that separates out the stem cells, and is returned through a needle in the other arm. Donors may not feel well during the donation, but generally make a full recovery immediately following the donation.

Umbilical-Cord Blood Stem-Cell Donor: Umbilical-cord blood contains large numbers of stem cells. After a baby’s birth, blood is collected from the placenta and umbilical cord. There is no physical effect on the mother or the infant.

Transplant Tourism
Each year the number of patients on a waiting list for transplantation exceeds the number of patients receiving transplants. An increase in the wait time for transplantation may result in increased risk for clinical deterioration,
reduced quality of life, and, in some cases, deaths of patients on the waiting list. This has led to an increase in the number of patients seeking organs from other countries for the purpose of transplant. Transplant tourism is the purchase of transplantation organs abroad which includes access to an organ while bypassing laws, rules or processes of any or all countries involved.

Most countries in the Western world prohibit compensated organ donation. Within the United States, the National Organ Transplant Act of 1972 states, “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation.” Penalties include a fine of up to USD $50,000 and/or imprisonment for up to five years. A policy proposal relating to transplantation of deceased-donor organs into nonresidents of the United States was jointly sponsored by the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) International Relations and Ethics Committees and approved by the OPTN/UNOS Board in June 2012 (Vella, 2019; Glazier, et al., 2014).

The American Society of Transplantation (AST) recently updated their guidelines on Travel Medicine, Transplant Tourism, and the Solid Organ Transplant Recipient. The guidelines review recommendations for prevention and management of travel-related infection in solid organ transplant (SOT) recipients as well as risks associated with transplant tourism (Buchan, et al., 2019).

The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative (2019)
No relevant information found.

Centers for Medicare & Medicaid Services (CMS)
- National Coverage Determinations (NCDs): No NCD found.
- Local Coverage Determinations (LCDs): No LCDs found.

Use Outside of the US
National Institute for Health and Care Excellence (NICE) has a 2011 guideline titled Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (CG135). It was updated in December 2016. It offers best practice advice on improving donor identification and consent rates.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
   2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01990</td>
<td>Physiological support for harvesting of organ(s) from brain-dead patient</td>
</tr>
<tr>
<td>32850</td>
<td>Donor pneumonectomy(s) (including cold preservation), from cadaver donor</td>
</tr>
<tr>
<td>32855</td>
<td>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</td>
</tr>
<tr>
<td>32856</td>
<td>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</td>
</tr>
<tr>
<td>33930</td>
<td>Donor cardiectomy-pneumonectomy (including cold preservation)</td>
</tr>
<tr>
<td>33933</td>
<td>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</td>
</tr>
<tr>
<td>33940</td>
<td>Donor cardiectomy (including cold preservation)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>33944</td>
<td>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</td>
</tr>
<tr>
<td>38204</td>
<td>Management of recipient hematopoietic progenitor cell donor search and cell acquisition</td>
</tr>
<tr>
<td>38205</td>
<td>Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic</td>
</tr>
<tr>
<td>38230</td>
<td>Bone marrow harvesting for transplantation; allogeneic</td>
</tr>
<tr>
<td>44132</td>
<td>Donor enterectomy (including cold preservation), open; from cadaver donor</td>
</tr>
<tr>
<td>44133</td>
<td>Donor enterectomy (including cold preservation), open; partial, from living donor</td>
</tr>
<tr>
<td>44715</td>
<td>Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein</td>
</tr>
<tr>
<td>44720</td>
<td>Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>44721</td>
<td>Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each</td>
</tr>
<tr>
<td>47133</td>
<td>Donor hepatectomy (including cold preservation), from cadaver donor</td>
</tr>
<tr>
<td>47140</td>
<td>Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)</td>
</tr>
<tr>
<td>47141</td>
<td>Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)</td>
</tr>
<tr>
<td>47142</td>
<td>Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)</td>
</tr>
<tr>
<td>47143</td>
<td>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</td>
</tr>
<tr>
<td>47144</td>
<td>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])</td>
</tr>
<tr>
<td>47145</td>
<td>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 (ie, left lobe [segments II, III, and IV] and right lobe [segments I and V through VIII])</td>
</tr>
<tr>
<td>47146</td>
<td>Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>47147</td>
<td>Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each</td>
</tr>
<tr>
<td>48550</td>
<td>Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation</td>
</tr>
<tr>
<td>48551</td>
<td>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</td>
</tr>
<tr>
<td>48552</td>
<td>Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each</td>
</tr>
<tr>
<td>50300</td>
<td>Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral</td>
</tr>
<tr>
<td>50320</td>
<td>Donor nephrectomy (including cold preservation); open, from living donor</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>50323</td>
<td>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</td>
</tr>
<tr>
<td>50325</td>
<td>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</td>
</tr>
<tr>
<td>50327</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>50328</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each</td>
</tr>
<tr>
<td>50329</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each</td>
</tr>
<tr>
<td>50547</td>
<td>Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor</td>
</tr>
</tbody>
</table>

**HCPCS Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>S2055</td>
<td>Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor</td>
</tr>
<tr>
<td>S2061</td>
<td>Donor lobectomy (lung) for transplantation, living donor</td>
</tr>
<tr>
<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
</tr>
<tr>
<td>S2152</td>
<td>Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition</td>
</tr>
<tr>
<td>S9975</td>
<td>Transplant related lodging, meals, and transportation, per diem</td>
</tr>
</tbody>
</table>


**References**


