



# Cigna Medical Coverage Policy

**Subject Transplantation Donor Charges**

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### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. 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. Proprietary information of Cigna. Copyright ©2013 Cigna

## Coverage Policy

**Cigna covers transplantation donor expenses 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.

**Cigna considers the following to be 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

**Cigna does not cover transplantation donor expenses for non-human organ transplants because transplantation coverage is limited to human organs and tissue under most plans, and because it is considered experimental, investigational or unproven.**

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## General Background

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 is defined as "the transplantation, implantation, or infusion into a human recipient of either live cells, tissues or organs from a nonhuman source to a human source, or human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs" (U.S. Public Health Service [PHS], 2001; Chapman, Bloom, 2001). 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 (e.g., hyperacute rejection, delayed rejection, and cellular rejection), difficulty controlling immune responses, and infectious disease issues (e.g., unrecognized infectious agents, retroviruses, zoonoses). 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. A consensus statement on the live organ donor, formulated by participants of a conference sponsored by the National Kidney Foundation, American Society of Transplantation, American Society of Transplant Surgeons, American Society of Nephrology, The United Network for Organ Sharing, and National Institutes of Health (2000), and others, recommends the following criteria for living organ donors:

- competent
- willing to donate
- free from coercion
- medically and psychosocially suitable
- fully informed of the risks and benefits as a donor
- fully informed of the risks, benefits and alternative treatment available to the recipient

Guidelines for the informed consent of living donors have been adopted by OPTN/UNOS (Organ Procurement and Transplantation Network/United Network for Organ Sharing). The informed consent guidelines include the assurance that the potential donor is willing to donate, is free from inducement or coercion, and understands that he/she can decline at any time (UNOS, 2009).

OPTN/UNOS has issued various other guidelines, including but not limited to those for the medical evaluation of potential living liver donors (OPTN/UNOS, 2010). In general, the guidelines for potential living donors include provisions for an independent donor team to educate and provide counseling, psychiatric and social screening, and appropriate medical and radiological evaluations.

Living-donor organ donation requires the donor to undergo surgery to remove the organ of donation. A medical evaluation of the donor is conducted prior to the procedure to ensure that the donor is an appropriate match and is physically fit enough to safely donate the organ. The surgical procedure is performed in the hospital, and the donor will require postoperative hospitalization. The length of hospitalization will depend upon the procedure performed and the donor's medical condition. Most donors do not have any long-term adverse effects from the donation. However, the benefits to the donor and the recipient must outweigh the risks of organ procurement and transplantation. Donors should not be called upon to donate in clinically hopeless situations.

### **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, 2010):

- between the ages of 18 and 60
- 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 (UNOS, 2007). According to the American Society of Transplantation (AST) and the board of directors at UNOS the practice of transplantation tourism is poorly regulated.

In 2006, UNOS adopted a position statement opposing the practice of transplantation tourism. In 2007, UNOS amplified their position and reported, "The UNOS Ethics Committee condemns the practice of transplantation tourism. Participation in such a practice cannot be defended on ethical or current empirical grounds." UNOS further reported it is the obligation of the transplantation community not only to condemn the practice but to endorse ethically defensible policies which would render such practices unnecessary.

The AST reported in a position statement on transplantation tourism (2007) that optimal medical care should not be withheld from those recipients who have chosen to receive transplantation as tourists from abroad; however, the AST has several concerns regarding transplantation tourism, which include the following:

- the circumstances surrounding the source of both living and deceased donor organs
- the quality of donor organs, as well as transplantation services
- the risk for transmission of infectious disease
- follow-up care post-transplant
- the serious ethical issues associated with all of the above concerns

The Transplantation Society (TTS), an organization for worldwide advancement of organ transplantation, holds the position that a practice that has no transparency or professional oversight violates ethical principles of care, and they are opposed to practices of transplantation tourism that exploit donors and recipients (TTS, 2006).

Despite concerns, however, UNOS and AST both agree that post-transplantation medical treatment should be provided to individuals who have received an organ through transplantation tourism.

**Use Outside of the US:** No relevant information was found related to transplantation donor charges.

### **Summary**

Donors of solid organs or stem cells must meet specific medical criteria in order to ensure the safety of the donor and the recipient. Solid-organ donation can be either from living or deceased (i.e., cadaveric) donors. Because of the shortage of deceased organs, living-donor organs have become more frequently utilized. However, the potential benefit to the recipient must outweigh the potential for harm to the donor in order for this

procedure to be beneficial. Stem cells from bone marrow, peripheral blood or umbilical-cord blood are used to replace stem cells from patients who, through disease or therapy, do not produce adequate numbers of their own stem cells. Xenotransplantation currently remains under investigation.

## 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.

### Covered when medically necessary:

CPT <sup>®</sup> * Codes	Description
01990	Physiological support for harvesting of organ(s) from brain-dead patient
32850	Donor pneumonectomy (including cold preservation), from cadaver donor
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
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
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
38204	Management of recipient hematopoietic progenitor cell donor search and cell acquisition
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogenic
38230	Bone marrow harvesting for transplantation; allogeneic
44132	Donor enterectomy (including cold preservation), open; from cadaver donor
44133	Donor enterectomy (including cold preservation), open; partial, 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
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 two 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 two partial liver grafts (ie, left lobe (segments II, III, and IV) and right lobe (segments I and 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
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
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

<b>HCPCS Codes</b>	<b>Description</b>
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor
S2061	Donor lobectomy (lung) for transplantation, living donor
S2140	Cord blood harvesting for transplantation, allogenic
S2152	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
S9975	Transplant related lodging, meals and transportation, per diem

**\*Current Procedural Terminology (CPT®) ©2012 American Medical Association: Chicago, IL.**

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