



Medical Coverage Policy

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Transplantation Donor Charges

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- [Intestinal and Multivisceral Transplantation](#)
- [Kidney Transplantation, Pancreas-Kidney Transplantation, and Pancreas Transplantation Alone](#)
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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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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:

- 104,234 is the number of men, women and children on the national transplant waiting list as of March 2023.
- 42,000+ transplants were performed in 2022
- 17 people die each day waiting for a transplant
- Every 10 minutes another person is added to the waiting list

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 FDA; 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. 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, 2023). 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 (OPTN policy 14.3, 8/1/2023)

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 (OPTN policy 14.3, 8/1/2023)

For any living 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. All ILDA requirements must be completed prior to organ recovery.

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.

4. Review and document whether the living donor has received information on numerous issues and assist the donor in obtaining additional information from other professionals as needed (OPTN Policy 14.2.A, 8/01/2023).

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.

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.

The National Marrow Donor Program "Be The Match®" Bone Marrow Donation Guidelines Medical Requirements for donating bone marrow exist to protect the health of donating and transplant patients.

- Be The Match® is focused on recruiting people ages 18 to 35 because medical research shows that younger donors are best for patients and provide the greatest chance for transplant success. Because of this, doctors prefer donors in the 18 to 35 age group.
- You are not able to join if you have an autoimmune illness that affects your whole body.
- You are not able to register if you have a serious bleeding problem such as hemophilia or Factor V Leiden, or if you have ever had a deep vein blood clot, require anticoagulant medications, have aplastic anemia, or Von Willbrand's Disease.
- If you have elevated blood pressure (hypertension), you may register if your condition is well-controlled by medication or diet and if there is no associated heart disease.
- If you have diabetes, a careful evaluation of your current health status will be necessary. In general, if your diabetes is well controlled by either diet or medications (other than insulin), you will be allowed to register. If you require insulin to treat diabetes or if you have diabetes-related serious health issues such as kidney, heart, nerve or eye disease, you will not be allowed to register.
- You may register if you have well-controlled epilepsy and have had no seizures in the past year.
- In general, if you have heart disease you cannot become a potential volunteer donor. This includes a past heart attack, any history of angioplasty, bypass surgery, heart valve replacement surgery or pacemakers. However, some heart conditions such as congenital defects surgically corrected in childhood, mitral valve prolapse (MVP) that is well controlled, or successful cardiac ablation will not prevent you from registering to become a donor.
- If you have history of a stroke, a transient ischemic attack (TIA), an intracranial hemorrhage (epidural, subdural, subarachnoid), or other significant brain injury or surgery in the brain tissue — even if currently recovered with no symptoms — you are not able to register.
- You will be allowed to join the Be The Match Registry if you have:
 - Received a vaccine to prevent hepatitis
 - History of fully-recovered hepatitis A
 - Close or intimate contact with someone with active hepatitis B or C in the past year
 - Possible exposure to hepatitis B or C in the past year
 - History of jaundice due to mononucleosis or cytomegalovirus (CMV) infection

- If you have the following, you cannot join the registry:
 - Diagnosed with hepatitis B or C
 - Been told you had a positive confirmatory test for hepatitis B or C
 - Been told you are a carrier of hepatitis B or C (also known as a “chronic” infection)
 - History of hepatitis or yellow jaundice (after age 11) without a known cause
- You cannot register if you have serious or chronic kidney problems such as polycystic kidney disease or chronic glomerulonephritis. If you have had a kidney removed due to disease, you cannot register. However, if you donated a kidney to another person and are now fully recovered from that surgery, you are able to register. You are able to register if you have a history of kidney stones.
- If you have received human tissues, such as bone (including bone powder for dental procedures), ligaments, tendons, skin and corneas, you may be allowed to register to become a potential volunteer donor, depending on the reason for the procedure.
- If you received any of the following types of transplants you may not register:
 - Human organs such as heart, lung, liver or kidney
 - Marrow or blood-forming cells
 - Xenotransplant (live tissues from animals)

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.

Disparities in Organ Donation

Organ donation is affected by legal, cultural, religious, and racial factors, as well as by health considerations.

- **Gender:** Although organs in and of themselves are gender neutral and can be exchanged between the sexes, women account for up to two thirds of all organ donations. Women’s willingness to donate their own organs to family members or strangers higher than men. More men than women are recipients, and women are less likely to complete the necessary steps to receive donated organs (Yee, et al., 2021; Steinman, et al., 2006).
- **Race:** Minority groups suffer from disparities in deceased and living donation. Barriers to minority deceased donation include: decreased awareness of transplantation, religious or cultural distrust of the medical community, fear of medical abandonment and fear of racism. African-Americans comprise only 11.8% of living donors. Barriers to minority living donation include: unwillingness to donate, medical comorbid conditions, trust or fear of medical community, loss to follow-up, poor coping mechanisms, financial concerns, reluctance to ask family members and friends, fear of surgery, and lack of awareness about living donor kidney transplantation. Interventions based upon an understanding of these barriers will need implementation culturally sensitive initiatives at a national level (Bratton, et al., 2011). A 1999 US study (Guadagnoli, et al., 1999) showed that Hospital staff approached 73% of families of patients for donation; however, families of White patients (79%) were approached more often than families of African Americans (67%) (P<.001). Of those families approached for donation, fewer than half (47%) agreed to donate an organ. Fewer (P< .001) families of African American patients (31%) agreed to donate organs than

did families of White patients (52%). Patients medically suitable for donation were: younger than 71 years, did not have a contraindication to organ donation, and met clinical criteria for brain death.

The U.S. Department of Health and Human Services' Office of Minority Health addresses Organ Donation and African Americans. The website notes:

- African Americans make up the largest group of minorities in need of an organ transplant. In 2021, non-Hispanic blacks made up 12.1% of the national population.
- The number of organ transplants performed on non-Hispanic blacks in 2021 was 27.8% of the number of non-Hispanic blacks currently waiting for a transplant. The number of transplants performed on non-Hispanic whites was 47.2% of the number currently waiting.
- While 28.6% of the total candidates currently waiting for transplants are non-Hispanic blacks, they comprised 15.1% of organ donors in 2021.
- In 2021, 81.3% of donor organs from non-Hispanic blacks were from deceased donors with 18.7% from living donors - as compared to 33.6% of white living donors.

(From the Office of Minority Health Resource Center website, September 2023).

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, 2022; Glazier, et al., 2014).

The American Society of Transplantation (AST) Statement on Organ Trafficking and Transplant Tourism (approved Feb 2023) defined transplant tourism, trafficking of persons for the purpose of organ removal and organ trafficking. The AST also noted these position statements:

- Trafficking in persons for the purpose of organ removal, organ trafficking and transplant tourism lead to significant and unacceptable human rights violations and are condemned by the AST. These practices lead to the exploitation of vulnerable persons who are the source of these organs, and the exploitation of vulnerable patients in need of lifesaving organ transplants who frequently suffer serious adverse health outcomes including death as a result of these unregulated, illegal transplants.
- Trainees must be aware that these issues may exist in their countries and practice ethically.
- Transplant journals must recognize and have policies to deal with research data derived from donors or recipients that have partaken in organ trafficking.

- The global transplant community must work together to prevent trafficking and exploitation of donors and recipients.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

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:

CPT®* Codes	Description
01990	Physiological support for harvesting of organ(s) from brain-dead patient
32850	Donor pneumonectomy(s) (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; allogeneic
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

CPT®* Codes	Description
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 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 (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

CPT®* Codes	Description
	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

HCPCS Codes	Description
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, allogeneic
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®) ©2022 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<ul style="list-style-type: none"> • No policy statement changes. 	11/15/2023

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