



Medical Coverage Policy

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Vascularized Composite Allograft (VCA) Transplantation

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Related Coverage Resources

- [Infertility Services](#)
- [Intestinal and Multivisceral Transplantation](#)

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 (CP) addresses vascularized composite allograft (VCA) transplantation. VCA transplant refers to the transfer of a vascularized human body part containing multiple tissue types as an anatomical and/or structural unit from a human donor to a human recipient.

For uterine transplantation, see Cigna Medical Coverage Policy "Infertility Services".

Coverage Policy

Vascularized composite allograft (VCA) transplantation is considered experimental, investigational or unproven.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Vascularized composite allograft (VCA) transplantation refers to the transfer of a vascularized human body part containing multiple tissue types as an anatomical and/or structural unit from a human donor to a human recipient. VCA transplants involve complex structures that may include organs, bone, muscle, skin, nerves, blood vessels and/or connective tissue. VCA is typically not a life-saving treatment; the goal of VCA is complete functional restoration. It is sometimes referred to as composite vascularized allograft (CVA).

Modern microsurgical techniques in combination with developments in transplant immunology have led to successful allotransplantation. Despite the increasing numbers and types of VCAs, patients who have received such allografts are necessarily maintained on various combinations of lifelong immunosuppressive regimens that are modeled after those used in solid organ transplantation. The potential sequelae of such chronic immunosuppression are well known. Patients who are recipients of VCA have developed myriad complications, including chronic allograft loss, metabolic disorders, renovascular dysfunction, opportunistic infections, and neoplasms.

The number of VCA transplants performed in the United States in recent years is low. Individual case reports or small case series have been published. It remains unknown whether the potential benefits to patients' quality of life outweigh the potential risks such as surgical complications, immunosuppression, opportunistic infections and psychiatric challenges. With hand transplants, data is needed comparing long-term transplant outcomes with use of limb prostheses. There is a paucity of supporting evidence in the peer-reviewed scientific literature; therefore, VCA is considered experimental, investigational or unproven.

Organ Procurement and Transplantation Network (OPTN)

The Organ Procurement and Transplantation Network (OPTN) ruled to include vascularized composite allografts (VCAs) as "covered human organs" effective in 2014. With that directive, the OPTN was charged with the oversight of VCA procurement and transplantation. In 2014, 20 VCA transplant programs were approved, 10 candidates were waiting for VCA transplants and three VCA transplants had been allocated through the OPTN. The 2014 OPTN Final Rule defined VCA transplantation as the transplant of any body part that meets the following nine criteria:

1. Vascularized and requires blood flow by surgical connection of blood vessels to function after transplant
2. Contains multiple tissue types
3. Recovered from a human donor as an anatomical/structural unit
4. Transplanted into a human recipient as an anatomical/structural unit
5. Minimally manipulated (ie, processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement)
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor)
7. Not combined with another article such as a device
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved
9. Susceptible to allograft rejection

Effective June 18, 2020, vascular composite allograft offers will first be made to compatible transplant candidates listed at VCA programs within a radius of 500 nautical miles (NM) of the donor. This replaces the previous distribution unit, which had been the OPTN region of the donor hospital.

In June 2021, 40 vascularized composite allograft (VCA) transplant programs across eight specialty categories were approved. The new, specialized VCA transplant program categories are:

- Upper limb
- Head (craniofacial allograft) and neck
- Abdominal wall
- Genitourinary organs
- Glands
- Lower limb
- Musculoskeletal composite graft segment
- Spleen

According to Organ Procurement and Transplantation Network (OPTN) National data:

Type	# transplants performed (January 1, 1988 - September 30, 2024)
Abdominal Wall	22 (starting in 2001; most recent: two in 2022)
Head & Neck: Craniofacial	19 (starting in 2008; most recent: one in 2023)

Type	# transplants performed (January 1, 1988 - September 30, 2024)
Head & Neck: Scalp	1 (in 2015)
Head & Neck: Larynx	2 (one in 1998, one in 2010)
GU: Penile	2 (one in 2016, one in 2018)
GU: Uterus	41 (17 deceased donors, 24 living donors; starting in 2016; most recent: two in 2023)
GU: Penile	2 (one in 2018, one in 2016)
Bilateral limb, Face	No data
Upper Limb: Bilateral	19 (starting in 2009; most recent: one in 2021)
Upper Limb: Unilateral	18 (starting in 1999; most recent: one in 2019)
Trachea	1 (2021)

(OPTN data for Transplants by Donor Type. Vascular Composite Allograft OPTN data as of September 13, 2023. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>)

OPTN/SRTR 2022 Annual Data Report: Vascularized Composite Allograft (Hernandez, et al., 2024):

- Section 3.3 VCA Transplant Other Than Uterus – Recipients: Of the total 56 listed nonuterus VCA candidates, 34 individuals (60.7%) underwent transplant in 2014-2022. There has been no substantial change in the number of nonuterus VCA transplants performed. Upper limb transplant was the most frequently performed (44.1%), followed by face (32.4%), abdominal wall (11.8%), penis (5.9%), scalp (2.9%), and Other/multiple (2.9%).

The age distribution of nonuterus VCA transplant recipients during this period was as follows: the most prevalent age group was 18-34 years (41.1%), followed by 50-64 years (26.5%), 35-49 years (20.6%), 65 years or older (8.8%), and younger than 18 years (2.9%). These recipients were stratified into two distinct categories for race and ethnicity data collection: White (27 of 34 [79.4%]) and non-White (7 of 34 [20.6%]). Among nonuterus VCA recipients during this period, males continued to make up the largest portion, accounting for 70.6% (24 of 34), while females were the remaining 29.4% (10 of 34).
- Section 3.4 VCA Transplant Other Than Uterus – Access and Outcomes: Currently, 21 programs in 11 states have performed nonuterus VCA transplant. When assessing the distribution of programs according to organ type, upper limb transplant emerges as the most prevalent procedure, with nine programs having performed it from 2014 through 2022. Face transplant has been carried out at five programs, and abdominal wall transplant has been done at three programs. Transplants in the Other/multiple category were performed at one program; penis and scalp transplant were conducted at two programs and one program, respectively. Compared with the previous year's report, there was an increase in the number of programs providing abdominal wall transplant from two to three. The examination of patient outcomes in nonuterus VCA transplant involved the classification of results into "functioning graft" and "failed graft." Over the recorded timeframe of 2014-2022, there was one occurrence of upper limb VCA failure reported (1 of 15 [6.7%]), while abdominal wall, face, Other/multiple, penis, and scalp VCA transplants were reported with a 100% functioning graft rate, similar to earlier observations (OPTN/Hernandez, et al., 2024).

Chronic Rejection

The American Society of Reconstructive Transplantation and International Society of Vascularized Composite Allotransplantation published a White Paper to define chronic rejection in recipients of

vascularized composite allografts, with an emphasis on upper extremity and face transplants (Kaufman, et al., 2020). The working group proposed the definition characterize four different levels of chronic rejection (CR):

Category of chronic rejection	Working definition	Proposed markers or evidence for category
CR0	Absence of any clinical or histologic evidence of CR	<ul style="list-style-type: none"> • Normal parameters for assays/tests described below
CR1	Histologic evidence of CR without functional decline or external evidence	<ul style="list-style-type: none"> • Capillary thrombosis and loss of microvasculature • Hair follicle apoptosis • Tertiary lymphoid organ-like follicles • C3d or C4d deposition? (de novo donor-specific antibody [DSA]?) • Histologic evidence for skin atrophy and adnexal loss • Fibrotic changes • Vasculopathy/intimal proliferation/hypertrophy on histology but not by magnetic resonance angiogram (MRA)/computed tomography angiography (CTA)/ultrasound (US)
CR2	Subclinical functional decline Clinical and histologic evidence of CR in the absence of functional decline of the graft	<ul style="list-style-type: none"> • Histologic evidence of skin atrophy/fibrosis • Histologic evidence of adnexal loss • Reduction of digital and wrist brachial indices (hand) • Vascular high-resolution ultrasound—availability, reproducibility? • MRA/CTA evidence of lumen narrowing • No significant (?) reduction in electromyography (EMG) or functional tests
CR3	Overt functional decline of graft with external and histologic evidence of chronic rejection	<ul style="list-style-type: none"> • Skin necrosis • Purpuric skin lesions/bruising • Adnexal loss • MRA/CTA luminal reduction (sensitive enough?) • Vascular high-resolution ultrasound—availability, reproducibility? • EMG nerve function? • Physical function decline (graft-specific, Carroll score, speech, etc.) • Pain • Supporting biopsy histology

Abdominal Wall Transplant

Abdominal wall transplantation (AWT) includes reconstruction of complex abdominal wall defects in conjunction with visceral organ transplantation. In some cases, the closure of the abdominal wall can be very difficult or even impossible due to repeated laparotomies or fistulae that make the abdominal wall unsuitable for closure, or to the prolonged absence of the midgut that leads to the loss of the domain of the abdominal compartment. Failure to close the abdomen leaves the recipient with an open wound or, at best, requires several surgical procedures for closure. As a consequence, intraabdominal infection, injury to organs and fistula formation can occur, leading to higher patient mortality. One of the major challenges presenting to the reconstructive surgeon is

time to revascularization of the donor abdominal wall. As of recently (2019), 38 cases of total AWT have been performed worldwide, about half of which were performed in the United States (Erdmann, et al., 2019; Cipriani, et al., 2007).

2003: Levi et al. (2003) reported on eight patients (four adults and four children) who underwent abdominal wall composite allograft transplantation. The decision to include an abdominal wall composite graft in patients undergoing intestinal transplantation was made if conventional abdominal closure was not possible. All patients had small abdominal compartments from previous surgical resections and severely damaged abdominal walls from previous incisions, wound infections, fistulae, and stomata. With the exception of two recipients, the abdominal wall grafts originated from the same donor as the intestinal graft and were transplanted concurrently with the intestinal graft. The blood supply was derived from the donor inferior epigastric vessels, left in continuity with the larger femoral and iliac vessels. At time of publication, six of the eight patients were alive; five had functioning, viable abdominal wall composites grafts. These five patients had been followed up for one, three, nine, 13, and 23 months post-transplant. No patient in this series had signs or symptoms of graft versus-host disease, and none died as a result of complications of the abdominal wall graft.

2007: Cipriani et al. (2007) reported on three consecutive cases of abdominal wall transplantation by direct anastomosis of the epigastric vessels. The authors noted their microsurgical technique leaves the donor iliac vessels available for vascular surgeons and seems not to increase the operative time or the risk of vascular accidents. They concluded that their early outcomes were encouraging and larger studies with a longer follow-up are needed to assess the safety of this procedure.

2014: Giele et al. (2014) reported on six cases of combined small bowel and abdominal wall transplantation. The ischemic time was minimized by remotely revascularizing the abdominal wall on the forearm vessels synchronous to the intestinal procedure. When the visceral transplant was complete, the abdominal wall was removed from the forearm and revascularized on the abdomen (n=4), or used to close the abdomen while still vascularized on the forearm (n=2). The authors reported one patient died at six weeks due to systemic sepsis, with a viable abdominal wall abdominal wall VCA. At time of publication, five patients were alive and well. The authors noted that although revascularization on the forearm did increase the complexity of the procedure overall, immediate forearm revascularization had a beneficial effect.

2020: In a review of the literature, Atia et al. (2020) identified four distinct revascularization techniques. The authors concluded that refinement of the identified methods will continue to evolve with greater available evidence and outcomes. Shortened ischemia time, ease of dissection, and fewer technical demands of AWT will all contribute to better outcomes for future patients.

Face Transplant

Risks versus benefits must be considered when making the decision to perform facial transplantation. The possible consequences of lifelong immunosuppression in otherwise healthy individuals—including cancer, metabolic disorders, opportunistic infections, and death—must therefore be carefully balanced to minimize risk and maximize benefit. The most important decision determining the success of facial transplantation remains patient selection. Rigorous preoperative psychiatric and psychological selection of patients deemed to be stable, motivated, and compliant by a multidisciplinary team is a crucial determinant of a safe and rapid recovery (Khalifian, et al., 2014).

2016: Lantieri et al. (2016) reported the long-term outcomes of six face allotransplant recipients at an average of six years (range 3.4–9 years) after the transplantation. A total of seven were

transplanted: two with neurofibromatosis 1, one with a burn, and four with self-inflicted facial gunshot injuries. Two of seven patients died: one at 65 days due to transplant destruction with concomitant pseudomonas infection and the second at 3.4 years after transplantation by suicide. Patients faced an average of three (range 1–6) revision surgeries. Recurrent rejection episodes justified maintenance therapy with high-dose steroids at high levels in all patients at last follow-up. Three patients were found to have hypertension with one requiring therapy. All patients had a noticeable reduction in glomerular filtration rate. None of the patients developed diabetes. The authors summarize that their long-term results show the crucial effect of patients' social support and pre-existing psychiatric conditions on the risk–benefit ratio of facial transplantation. They recommend careful preoperative patient selection and long-term postoperative follow-up programs under strict institutional review board controls should be used for any future grafts of this type.

2021: Tchiloemba et al. (2021) conducted a systematic review of facial VCAs (fVCA) including 23 patients from six different medical institutions worldwide (in 28 articles). The mean follow-up was 5.3 ± 1.9 years. The most common mechanism of injury was ballistic trauma (43.5%), followed by burns (30.4%). Compared to pretransplant state, more than 50% of patients had improvements in quality of life (QoL), eating, speech, and motor and sensory functions. Overall, the patients had 0.92 acute rejection episodes per 1 transplant year (TY). For both acute rejection and infectious episodes, the incidence rates decreased after the first posttransplant year. Transient nephrotoxic episodes (30.4%), dyslipidemia (21.7%), chronic kidney disease (13.0%), hypertension (13.0%), and diabetes mellitus (13.0%) were among the most commonly developed metabolic complications postoperatively. Posttransplant lymphoproliferative disease, lung cancer, and in situ cervix carcinoma presented all equally in 4.3% of the patients. Chronic vascular rejections were confirmed in two patients and led to allograft loss after eight and nine years. Two patients died after nine and four years postoperatively due to lung cancer and suicide, respectively.

2021: Gray et al. (2021) conducted a systematic review and meta-analysis on vascularized composite allotransplantation employed for burn reconstruction (n=45 face transplants). The authors stated that the use of VCA in burn patients has potential additional complexities that must be considered. The authors noted that observational meta-analysis of pooled mortality and acute rejection episodes relative to allograft type (face vs. extremity) and reconstruction type (burn vs. non-burn) was performed. Twenty-four of the 63 identified articles met the criteria for inclusion, with five more articles added after secondary review. At time of publication, 152 allotransplantations had been performed in 117 patients: 45 face transplants and 107 upper extremity transplants. Of these, 34 (22%) were performed for burn reconstruction in 25 patients (21%) with an overall higher 1-year mortality rate (12.0% vs 1.1%, $p=0.030$). Of these deaths, 75% received three or more simultaneous allografts. Additionally, more episodes of acute rejection occurred compared to non-burn patients (4.4 vs 2.4, $p=0.035$). Vascularized composite allotransplantation performed for burn reconstruction was found to be associated with a greater risk of 1-year mortality and nearly twice the number of episodes of acute rejection.

2021: Diep et al. (2021) performed a literature review and reported that to date, 48 face transplants have been performed on 46 recipients. The most common indications for face transplant (FT) were craniofacial defects from ballistic trauma (43.7%), followed by thermal, chemical, or electrical burn injuries (25.0%). Despite the paucity of long-term outcome reports, the data available indicate that most FT recipients remained alive at time of writing (81.2%), while 8 (16.7%) had died. Diep et al. commented that with FT recipients now living longer post-transplant, there will be an increasing number of chronic rejection (CR) and allograft failure. With some facial allografts beginning to succumb to CR, FT teams are challenged to innovate with re-transplantation to overcome new hurdles. Regarding combined face and double hand transplant (FT-DHT), Diep et al. stated although there have been two unsuccessful attempts at combined FT-

DHT reported in the past; in August 2020, the world's first successful combined FT-DHT was performed in a 21-year-old man who had sustained an 80% total body surface area burn injury.

2023: Longo et al. (2023a) conducted a systematic literature review to provide an updated review on complications and major challenges witnessed over 18 years of experience in the field. There were 28 articles included. On a total of 48 procedures performed in 46 patients, adverse outcomes were gleaned in 14 cases (29%), including seven allograft losses (14.6%), and the death of ten patients (21.7%). Chronic rejection was the leading cause of allograft loss, with a median time from transplant to irreversible rejection of 90 months. The main causes of death were infectious complications, followed by malignancies, non-compliance to immunosuppression, and suicide. The median time to death was 48.5 months.

Longo et al. (2023b) authored the "International consensus recommendations on face transplantation: A 2-step Delphi study". There were 35 experts including members of 10 FT teams, with a representation of 35 out of the 48 FTs performed (73%). Statements reaching consensus were shared with and approved by the panel before the drafting of recommendations. A total of 52 recommendations were produced and arranged in the following categories:

- Patient assessment and selection
- Indications
- Social support networks
- Clinical framework
- Surgical considerations
- Data on patient progress and outcomes
- Definitions of failure and success
- Public image and perception
- Financial sustainability

Hand Transplant

2003: Dubernard et al. (2003) reported on the first human double-hand transplantation which was performed in Lyon, France. The individual was a 33-year-old man who suffered an amputation of both hands in 1996 after a blast injury; the stump level was 3 cm above the wrist. No early or late surgical complications occurred. Physiotherapy started 12 hours after surgery twice daily for the first year post-transplantation. By one year post-transplant, the patient was able to perform the same daily activities that were possible with the myoelectric prostheses before the transplantation. In addition, several activities such as holding a pen or a glass or a pair of scissors, shaving, and taking care of his personal hygiene that were impossible before were then easily performed by the patient.

2015: Bernardon et al. (2015) reported on a total of five adults who received bilateral hand-forearm allografts performed by the Lyon, France (Dubernard, et al. 2003) team. Over a mean follow-up period of 7.6 years (range 4-13 years), restoration of motion, strength, and sensibility were fair. Functional results (Carroll upper extremity function test, 400-point test, activities of daily living) as well as quality of life evaluation (RAND-36) were good. Two out of five patients returned to work. Subjective and overall results explored with questionnaires - Disabilities of the Arm Shoulder and Hand (DASH), Hand Transplantation Score System (HTSS), were very good. Improvement was seen to continue during the first three years, and then tended to become stable. The overall results were effective, unequalled by prosthesis so far, and lasting for the duration of the follow-up.

2020: Hautz et al. (2020) reported on five patients who received bilateral hand (n=3), bilateral forearm (n=1), and unilateral hand (n=1) transplants at the Innsbruck Medical University Hospital (Austria) between 2000 and 2014. During the 6–20 years follow-up, 43 rejection episodes were

recorded in total. In the long-term, a change in hand appearance was observed. The functional outcome was highly depending on the level of amputation. The number and severity of rejections did not correlate with hand function, but negatively impacted on the patients' well-being and quality of life. Patient satisfaction significantly correlated with upper limb function. One hand allograft eventually developed severe allograft vasculopathy and was amputated at seven years. The patient later died due to progressive gastric cancer. The other four patients were rejection-free with moderate levels of immunosuppression. The authors concluded that hand transplantation remains a therapeutic option for carefully selected patients.

2021: Gray et al. (2021) conducted a systematic review and meta-analysis on vascularized composite allotransplantation employed for burn reconstruction (n=107 upper extremity transplants). The authors stated that the use of VCA in burn patients has potential additional complexities that must be considered. The authors noted that observational meta-analysis of pooled mortality and acute rejection episodes relative to allograft type (face vs. extremity) and reconstruction type (burn vs. non-burn) was performed. Twenty-four of the 63 identified articles met the criteria for inclusion, with five more articles added after secondary review. At time of publication, 152 allotransplantations had been performed in 117 patients: 45 face transplants and 107 upper extremity transplants. Of these, 34 (22%) were performed for burn reconstruction in 25 patients (21%) with an overall higher 1-year mortality rate (12.0% vs 1.1%, p=0.030). Of these deaths, 75% received three or more simultaneous allografts. Additionally, more episodes of acute rejection occurred compared to non-burn patients (4.4 vs 2.4, p=0.035). Vascularized composite allotransplantation performed for burn reconstruction was found to be associated with a greater risk of 1-year mortality and nearly twice the number of episodes of acute rejection.

Professional Societies/Organizations: The American Society for Surgery of the Hand (ASSH) Council published a Position Statement on Hand Transplantation (2013) which states "At this time, the American Society for Surgery of the Hand recognizes that hand transplantation represents an alternative to prosthetic fitting and rehabilitation in appropriately selected patients. However, advances should continue to be made in the areas of patient selection, surgical technique, and immunosuppression. Additional challenges include the funding of patients for these procedures and for lifelong immunosuppressive treatment. This procedure may have substantial merit in properly selected recipients. Nevertheless, for the present it should be carried out only in centers with extensive experience in both hand surgery and solid organ transplantation".

Lower Extremity Transplant

2013: Cavadas et al. (2013) reported on a case of bilateral transfemoral lower extremity transplantation. The 22-year-old male had suffered a bilateral traumatic above knee amputation in a car crash two years before. At one year, there was active knee extension and active plantar flexion of the foot. The patient was walking between parallel bars with rigid ankle-foot orthoses used for walking exercises. However, fifteen months post-transplantation, the patient developed primary central nervous system posttransplant lymphoproliferative disorder (PTLD), which required cessation of immunosuppression therapy and the removal of both legs (Cavadas, et al., 2015).

Penis Transplant

Reported potential indications for penile transplant may include, but are not limited to, traumatic loss, patients undergoing treatment for penile cancer, and patients with congenital conditions resulting in a small or abnormal phallus. It has been estimated that 1,367 military servicemen had genital injuries between 2001–2013 while serving in Iraq and Afghanistan. Contemporary body armor results in increased survival, with many patients sustaining complex injuries requiring advanced reconstructive and prosthetic interventions. In the injured military population, both the radial forearm free flap and the pedicled anterolateral thigh flap for neophalloplasty may not be

available to serve for reconstruction in patients who may have concomitant limb damage (Szafran, et al., 2018).

2017: van der Merwe et al. (2017) reported on a 21-year-old man who had been rendered aphallic three years previous to the penis transplantation following a ritual circumcision complicated by gangrene of the pendulous penis, depriving him of all the normal functions of a penis. At 24 months after the operation, the patient was doing well with no episodes of rejection. He reported regular satisfactory sexual intercourse in a stable relationship with normal ejaculation and orgasm. The authors reported the surgery resulted in restoration of sexual function, penile sensation, and normal urination. They emphasized the importance of careful patient selection in terms of physical health, emotional and psychological stability, and adherence to treatment.

2018: In a single case report, Cetrulo et al. (2018) described the first successful penis transplant in the United States in a patient with a history of subtotal penectomy for penile cancer. Maintenance immunosuppression consisted of mycophenolate mofetil, tacrolimus, and methylprednisolone. Steroid resistant-rejection developed on postoperative day (POD) 28 (Banff I), progressed by POD 32 (Banff III), and required a repeat course of methylprednisolone and antithymocyte globulin. At six months postoperatively, the patient described recovered sensation in the proximal penile shaft. He voided with excellent stream and low post-void residual volumes. In addition, he reported spontaneous partial erectile function with increasing quality and frequency.

2019: Redett et al. (2019) reported on a case of total penis, scrotum, and lower abdominal wall transplantation. The individual had sustained blast injury including above knee amputation of both legs, substantial tissue loss in the lower abdominal wall, traumatic penile loss, and bilateral traumatic orchiectomy and loss of the scrotum. After more than a year post-transplant, the individual had returned to school full time and continued to live independently using leg prostheses. The patient urinated while standing, without straining, frequency, or urgency, with the urine discharged in a strong stream. He had near-normal erections and the ability to achieve orgasm.

Uterus Transplant

See Cigna Medical Coverage policy "Infertility Services" for information on uterine transplantation.

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 since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven when used to represent vascularized composite allograft (VCA) transplantation:

CPT®* Codes	Description
21299	Unlisted craniofacial and maxillofacial procedure
21499	Unlisted musculoskeletal procedure, head
22999	Unlisted procedure, abdomen, musculoskeletal system
26989	Unlisted procedure, hands or fingers
55899	Unlisted procedure, male genital system

***Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL**

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<https://www.plasticsurgery.org/for-medical-professionals/health-policy/guiding-principles>
<https://www.plasticsurgery.org/for-medical-professionals/health-policy/position-statements>
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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 	01/15/2025
Annual review	<ul style="list-style-type: none"> No policy statement changes 	01/15/2024

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