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 addresses vascularized composite allograft (VCA) transplantation.

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

Coverage Policy

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

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and 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

General Background

Vascularized composite allograft (VCA) transplantation refers to the transfer of a human body part containing multiple tissue types, as an anatomical unit, from a human donor to a human recipient. The allograft may be composed of skin, muscle, bone, nerves, and connective tissue. Successful transplantation requires restoration of blood supply and lifelong immunosuppression. Unlike traditional solid organs, VCAs are primarily intended to restore form and function rather than to

prolong life. Examples of VCA transplants include the face, hand, abdominal wall, lower extremity, and penis.

The number of VCA transplants performed in the United States is low. Between 2014 and 2022, 34 individuals underwent non-uterus VCA transplantation (Hernandez et al., 2024). Current peer-reviewed evidence on VCA transplantation is limited and primarily consists of individual case reports and small case series. Existing systematic reviews are constrained by the limitations of the available studies, which substantially weaken the strength of the conclusions. High-quality comparative data evaluating long-term outcomes in hand and limb transplantation versus prosthetics are also lacking. It remains uncertain whether the potential benefits of VCA transplantation, such as functional restoration and improved quality of life (QOL), outweigh the significant risks, including surgical complications, chronic immunosuppression, opportunistic infections, and psychiatric challenges. Given the limited clinical experience, lack of robust high-quality evidence, and unresolved questions regarding safety, efficacy, long-term outcomes, and risk-benefit balance, VCA transplantation is considered experimental, investigational, or unproven.

U.S. Food and Drug Administration (FDA)

The FDA does not regulate the transplantation of vascularized human organs, which includes VCAs. The Organ Procurement and Transplantation Network (OPTN), overseen by the Health Resources and Services Administration (HRSA), within the U.S. Department of Health and Human Services (HHS), has regulatory authority over the procurement and transplantation of VCAs. The United Network for Organ Sharing (UNOS) helps manage the national transplant system.

VCAs are defined by Title 42 Part 121 of the Code of Federal Regulations: "A body part that is (1) Vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation; (2) containing 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 (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement—examples of minimal manipulation include cutting, grinding, and shaping of a VCA); (6) for homologous use (i.e., 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, e.g., a hand from the donor is to be used as a hand in the recipient); (7) not combined with another article such as a device; (8) susceptible to ischemia and, therefore, only stored temporarily (e.g., cold storage in preservation medium and intended for implantation into a recipient within hours of the recovery) and not cryopreserved; and (9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient."

Literature Review

<u>Abdominal Wall Transplant</u>

Current peer-reviewed evidence on abdominal wall transplantation is limited and primarily consists of individual case reports and small case series (e.g., Erdmann, et al., 2019; Giele, et al., 2014; Cipriani, et al., 2007; Levi, et al., 2003). Existing systematic reviews are constrained by the limitations of the available studies, which substantially weaken the strength of the conclusions (e.g., Reed, et al., 2022).

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 VCA. At the 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.

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.

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 and five had functioning, viable abdominal wall composites grafts. These five patients were followed up at 1-, 2-, 9-, 13-, and 23-months post-transplant. No patient in this series had signs or symptoms of graft versus-host disease, and none died because of complications from the abdominal wall graft.

Face Transplant

Current peer-reviewed evidence on face transplantation remains limited and primarily consists of individual case reports, small case series, and retrospective cohort studies (e.g., Homsy et al., 2024; Lantieri, et al., 2016). Existing systematic reviews are constrained by the limitations of the available studies, which substantially weaken the strength of the conclusions (e.g., Milek, et al., 2023; Longo, et al, 2023; Tchiloemba, et al., 2021; Gray, et al., 2021).

Milek et al., (2023) conducted a systematic review of the reported complications related to facial and upper extremity transplantation. The systematic review included 65 studies of 115 patients who underwent VCA implantation between 1998 and 2021. Of the total, 49 patients underwent face transplantation and 66 underwent upper extremity transplantation. Three patients underwent simultaneous face and bilateral upper extremity transplantation. The systematic review included studies reporting and evaluating face and upper extremity transplantation complications and outcomes. The primary outcomes of interest were surgical complications, acute and chronic allograft rejection, opportunistic infections, and immunosuppression therapy related complications, other than infection. Length of follow-up was not reported. The study results revealed an average patient age of 37.4 years (range: 8 to 68). Most patients were male (80%). Acute surgical complications occurred in 23% of patients, 26% for face transplants and 21% for upper extremity transplants. Vascular anastomosis thrombosis was the most common acute surgical complication for both groups (14%). Acute rejection occurred in 89% of patients, 86% for face transplants and 92% for upper extremity transplants. Chronic rejection occurred in 11% of patients, 14% for face transplants and 8% for upper extremity transplants. Opportunistic infections occurred in 58% of patients, 68% for face transplants and 52% for upper extremity transplants. Neoplastic findings occurred in 7% of patients, 10% for face transplants and 5% for upper extremity transplants. The authors concluded that face and upper extremity transplantation remain a viable option for

patients with major structural or functional defects that cannot be restored with conventional reconstruction techniques. However, the complications related to VCA were a significant source of morbidity and potential mortality. The incidence of complications was also higher than previously reported. Strict patient selection, comprehensive preoperative evaluation, consideration of alternatives, and a thorough discussion of risks with potential candidates should be performed prior to VCA implantation. The authors noted that a major limitation of the systematic review was disparity in the reporting of VCA outcomes. Only patients with clearly reported complications were included in this review. Patients with no reported specific complications were excluded. This may have resulted in under or over representation of outcomes. Additionally, the systematic review did not include a quantitative assessment of the quality of the included studies, did not report statistical significance for outcomes, and did not perform a meta-analysis.

Homsy et al. (2024) conducted a retrospective multicenter cohort study to evaluate global data on face transplant graft survival and episodes of acute rejection. The study included data from the first 50 patients in the world to have received a face transplant in 18 centers across 11 countries between 2005 and 2021. Data from 2005 until 2023 were included. The primary outcome was overall face transplant graft survival, defined as either transplant loss or patient death. The secondary outcome was episodes of acute rejection per year. The median follow-up time was 8.9 years (range: 0.2 to 16.7). The study results revealed 81% of transplants were performed on men and 19% on women. The median age was 35 years (range: 19 to 68) at the time of the transplant. During follow-up, six transplants were lost. Two patients were retransplanted. There were 10 patients who died. Two of these patients had lost a transplant. The 5- and 10-year survival of the transplants was 85% (standard deviation [SD] 5%) and 74% (SD 7%), respectively. However, the sequential number of the transplant was a significant predictor of survival (hazard ratio 95; 95% confidence interval, 90 to 100; $p<0.05$). The median number of acute rejection episodes per year was 1.2 (range: 0 to 5.3) for transplants that were lost and 0.7 (range: 0 to 4.6) for transplants that survived. No correlation with patient and transplant variables was observed for either transplant survival or episodes of acute rejection. The authors concluded that face transplant grafts demonstrated a promising survival rate. However, further transplants are needed to elucidate factors associated with increased risk of transplant loss. There were several study limitations noted by the authors. The study included a relatively small number of patients, transplant losses, and deaths which limit the reliability of the analysis. Subgroup analyses assessing the impact of the type or reason for the transplant or the antirejection drug protocols used were underpowered. Rejection episodes were less consistently reported. Data on the timing of the rejection episodes were not available. For reasons of data protection, collection could not be conducted by a fixed research team but instead was based on the data provided by the individual centers.

Longo et al. (2023) 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.

Tchiloemba et al. (2021) conducted a systematic review of facial VCAs, 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 QOL, eating, speech, and motor and sensory functions. Overall, the patients had 0.92 acute rejection episodes per transplant year. For both acute rejection and infectious episodes, the incidence rates

decreased after the first post-transplant 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. Post-transplant 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.

Gray et al. (2021) conducted a systematic review and meta-analysis on VCA transplantation 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 versus extremity) and reconstruction type (burn versus 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 versus 2.4, p=0.035). VCA transplantation 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.

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

Hand Transplant

Current peer-reviewed evidence on hand transplantation is limited and primarily consists of individual case reports and small case series (e.g., Hautz, et al., 2020; Schneeberger, et al, 2020; Dubernard, et al., 2003; Jones, et al., 2000). Existing systematic reviews are constrained by the limitations of the available studies, which substantially weaken the strength of the conclusions (e.g., Wells, et al., 2022; Gray, et al., 2021). High-quality comparative data evaluating long-term outcomes in hand transplantation versus prosthetics are also lacking (e.g., Burdon, et al., 2025; Efanov, et al., 2022; Bernardon, et al., 2015).

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 versus extremity) and reconstruction type (burn versus 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% versus 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 versus 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.

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 to 20 years of 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 dependent 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 QOL. 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.

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 to 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 QOL evaluation (RAND-36) were good. Two out of five patients returned to work. Subjective and overall results explored with standardized questionnaires 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.

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.

Professional Societies/Organizations

American Society for Surgery of the Hand (ASSH): The ASSH Council (2013) published a position statement on hand transplantation 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

Current peer-reviewed evidence on lower extremity transplant is limited and primarily consists of individual case reports (e.g., Cavadas, et al., 2015; Cavadas, et al., 2013). High-quality comparative data evaluating long-term outcomes in lower extremity transplantation versus prosthetics are also lacking.

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, after fifteen months post-transplantation, the patient developed primary central nervous system posttransplant lymphoproliferative disorder, which required cessation of immunosuppression therapy and the removal of both legs (Cavadas, et al., 2015).

Penis Transplant

Current peer-reviewed evidence on penis transplant is limited and primarily consists of individual case reports (e.g., Redett, et al., 2019; Cetrulo, et al., 2018; van der Merwe, et al., 2017).

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.

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.

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 that 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.

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.

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)

References

1. American Society for Surgery of the Hand Council. ASSH position statement on hand transplantation 2013. J Hand Surg Am. Nov 2013; 38(11): 2234-5.

2. Bernardon L, Gazarian A, Petruzzo P, Packham T, Guillot M, et al. Bilateral hand transplantation: Functional benefits assessment in five patients with a mean follow-up of 7.6 years (range 4-13 years). J Plast Reconstr Aesthet Surg. 2015 Sep;68(9):1171-83.

3. Burdon J, Taplin S, Leonard DA, Natalwala I, Bourke G, Kay SP. UK Hand and Upper Limb Transplant Service, functional outcomes of the first six patients: A case series. J Hand Surg Eur Vol. 2025 Sep;50(8):1008-1015.

4. Cavadas PC, Thione A, Blanes M, Mayordomo-Aranda E. Primary Central Nervous System Posttransplant Lymphoproliferative Disease in a Bilateral Transfemoral Lower Extremity Transplantation Recipient. Am J Transplant. 2015 Oct;15(10):2758-61.

5. Cavadas PC, Thione A, Carballeira A, Blanes M. Bilateral transfemoral lower extremity transplantation: result at 1 year. Am J Transplant. 2013 May;13(5):1343-9.

6. Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. Accessed September 19, 2025. Available at URL address: https://www.cms.gov/medicare-coverage-database/search.aspx

7. Cetrulo CL Jr, Li K, Salinas HM, Treiser MD, Schol I, et al. Penis Transplantation: First US Experience. Ann Surg. 2018 May;267(5):983-988.

8. Cipriani R, Contedini F, Santoli M, Gelati C, Sgarzani R, et al. Abdominal wall transplantation with microsurgical technique. Am J Transplant. 2007 May;7(5):1304-7.

9. Dubernard JM, Petruzzo P, Lanzetta M, Parmentier H, Martin X, et al. Functional results of the first human double-hand transplantation. Ann Surg. 2003 Jul;238(1):128-36.

10. Efanov JI, Izadpanah A, Bou-Merhi J, Lin SJ, Danino MA. Applying Health Utility Outcome Measures and Quality-Adjusted Life-Years to Compare Hand Allotransplantation and

Myoelectric Prostheses for Upper Extremity Amputations. Plast Reconstr Surg. 2022 Mar 1;149(3):465e-474e.

11. Erdmann D, Atia A, Phillips BT, Mithani SK, Avashia YJ, et al. Small bowel and abdominal wall transplantation: A novel technique for synchronous revascularization. Am J Transplant. 2019 Jul;19(7):2122-2126.

12. Genden EM, Miles BA, Harkin TJ, DeMaria S, Kaufman AJ, et al. Single-stage long-segment tracheal transplantation. Am J Transplant. 2021 Oct;21(10):3421-3427.

13. Giele H, Bendon C, Reddy S, Ramcharan R, Sinha S, et al. Remote revascularization of abdominal wall transplants using the forearm. Am J Transplant. 2014 Jun;14(6):1410-6.

14. Gray KM, Peterson JM, Padilla PL, Smith JM, Zapata-Sirvent RL, et al. Vascularized Composite Allotransplantation in Burn Reconstruction: Systematic Review and Meta-analysis. J Burn Care Res. 2021 May 7;42(3):465-472.

15. Hautz T, Messner F, Weissenbacher A, Hackl H, Kumnig M, et al. Long-term outcome after hand and forearm transplantation - a retrospective study. Transpl Int. 2020 Dec;33(12):1762-1778.

16. Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS). Organ Procurement and Transplantation Network. Final Rule. 42 CFR Part 121. Federal Register. 2013 Jul 3;78(128):40033-41. Accessed September 19, 2025. Available at URL address: https://www.federalregister.gov/d/2013-15731

17. Hernandez JA, Miller JM, Emovon E 3rd, Howell JN, Testa G, Israni AK, Snyder JJ, Cendales LC. OPTN/SRTR 2022 Annual Data Report: Vascularized Composite Allograft. Am J Transplant. 2024 Feb;24(2S1):S534-S556.

18. Homsy P, Huelsboemer L, Barret JP, Blondeel P, Borsuk DE, Bula D, Gelb B, Infante-Cossio P, Lantieri L, Mardini S, Morelon E, Nasir S, Papay F, Petruzzo P, Rodriguez E, Özkan Ö, Özmen S, Pomahac B, Lassus P. An Update on the Survival of the First 50 Face Transplants Worldwide. JAMA Surg. 2024 Dec 1;159(12):1339-1345.

19. Jones JW, Gruber SA, Barker JH, Breidenbach WC. Successful hand transplantation. One-year follow-up. Louisville Hand Transplant Team. N Engl J Med. 2000 Aug 17;343(7):468-73.

20. Kaufman CL, Kanitakis J, Weissenbacher A, Brandacher G, Mehra MR, et al. Defining chronic rejection in vascularized composite allotransplantation-The American Society of Reconstructive Transplantation and International Society of Vascularized Composite Allotransplantation chronic rejection working group: 2018 American Society of Reconstructive Transplantation meeting report and white paper Research goals in defining chronic rejection in vascularized composite allotransplantation. SAGE Open Med. 2020 Jul 14;8:2050312120940421.

21. Lantieri L, Grimbert P, Ortonne N, et al. Face transplant: Long-term follow-up and results of a prospective open study. Lancet. 2016;388(10052):1398-1407.

22. Levi DM, Tzakis AG, Kato T, Madariaga J, Mittal NK, et al. Transplantation of the abdominal wall. Lancet. 2003 Jun 28;361(9376):2173-6.

23. Longo B, Pomahac B, Giacalone M, Cardillo M, Cervelli V. 18 years of face transplantation: Adverse outcomes and challenges. J Plast Reconstr Aesthet Surg. 2023 Sep 15;87:187-199.

24. Milek D, Reed LT, Echternacht SR, Shanmugarajah K, Cetrulo CL Jr, Lellouch AG, Langstein HN, Leckenby JI. A Systematic Review of the Reported Complications Related to Facial and Upper Extremity Vascularized Composite Allotransplantation. J Surg Res. 2023 Jan;281:164-175.

25. Redett RJ 3rd, Etra JW, Brandacher G, Burnett AL, Tuffaha SH, et al. Total Penis, Scrotum, and Lower Abdominal Wall Transplantation. N Engl J Med. 2019 Nov 7;381(19):1876-1878.

26. Reed LT, Echternacht SR, Shanmugarajah K, Hernandez R, Langstein HN, Leckenby JI. Twenty Years of Abdominal Wall Allotransplantation: A Systematic Review of the Short- and Long-Term Outcomes. Plast Reconstr Surg. 2022 Nov 1;150(5):1062e-1070e.

27. Schneeberger S, Petruzzo P, Morelon E, Hautz T, Kanitakis J, et al. 20-Year Follow-up of Two Cases of Bilateral Hand Transplantation. N Engl J Med. 2020 Oct 29;383(18):1791-1792.

28. Szafran AA, Redett R, Burnett AL. Penile transplantation: the US experience and institutional program set-up. Transl Androl Urol. 2018 Aug;7(4):639-645.

29. Tchiloemba B, Kauke M, Haug V, Abdulrazzak O, Safi AF, et al. Long-term Outcomes After Facial Allotransplantation: Systematic Review of the Literature. Transplantation. 2021 Aug 1;105(8):1869-1880.

30. van der Merwe A, Graewe F, Zühlke A, et al. Penile allotransplantation for penis amputation following ritual circumcision: a case report with 24 months of follow-up. Lancet 2017; 390: 1038-47.

31. Wells MW, Rampazzo A, Papay F, Gharb BB. Two Decades of Hand Transplantation: A Systematic Review of Outcomes. Ann Plast Surg. 2022 Mar 1;88(3):335-344.

Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No clinical policy statement changes.	01/15/2026
Annual review	• No policy statement changes	01/15/2025
Annual review	• No policy statement changes	01/15/2024