Elevance Health FINAL DRAFT – LOGO TO BE INSERTED UPON FINAL PRODUCTION DATE

Medical Policy

Subject:	Hand Transplantation		
Document#:	TRANS.00040	**Publish Date:**	10/05/2022
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Description/Scope

This document addresses hand transplantation for individuals with an amputated hand. Hand transplantation is a type of vascularized composite allograft (VCA) allogenic transplantation involving multiple tissue types such as skin, connective tissue, blood vessels, bone, muscle and nerves. The goal of hand transplantation is functional restoration, rather than survival.

Note: Please see the following related document for additional information:

- **CG-OR-PR-05 Myoelectric Upper Extremity Prosthetic Devices**

Position Statement

Investigational and Not Medically Necessary:

Hand transplantation is considered investigational and not medically necessary.

Rationale

A 2022 systematic review by Wells and colleagues identified 98 individuals who received 148 hand transplants (44 unilateral and 52 bilateral) between 1998 and 2019. Data on acute rejection episodes were available for 57 individuals who had a mean follow-up of 72 months (range, 2 months to over 10 years). The number of rejection episodes for these 57 individuals ranged from 0 to 13, and 28% of individuals

experienced one episode. The median onset of the first episode of rejection was 55 days after transplantation (range, 3 days to 54 months). Chronic rejection was reported for 5 individuals. Functional outcomes were most consistently measured using the Disabilities of the Arm, Shoulder and Hand (DASH) score, scored from 0 (no disability) to 100 (most severe disability). Preoperative and postoperative DASH scores were available for 31 transplants in 18 individuals. In these individuals, the median preoperative DASH score was 71 (range, 25 to 100) and the median postoperative DASH score was 31 (range, 7 to 86). DASH scores decreased (improved) significantly after transplantation, p<0.001. Sensory recovery measured by the Semmes-Weinstein monofilament test was reported for 30 transplants and there was a median score of 4.06 mm. Grip strength, reported for 22 transplants, was a mean of 9.7 kg (range, 0.3 to 20kg). Sixteen of the 148 hand transplants (10.8%) were amputated during follow-up. The most common factor leading to amputation, in 33% of the cases, was acute rejection following immunosuppression withdrawal. Other factors included chronic rejection, distal ischemia, septic shock and intraoperative arterial thrombosis.

In 2020, Hein and colleagues published a review of hand transplants in the United States using data collected by the Organ Procurement and Transplantation Network (OPTN). The authors reviewed data from 1999 through 2018. They identified a total of 32 individuals who received hand transplants in the United States, 22 prior to July 3, 2014, and another 10 between that time and December 31, 2018. Outcome data were reported for the individuals who received transplants after July 3, 2014. DASH scores were available for 6 of the 10 individuals. At baseline, DASH scores ranged from 42 to 72 and, at the latest follow-up point, DASH scores ranged from 43 to 82. Three individuals had a decrease in DASH scores, 1 had an increase in the score and the other 2 had only one data point. Semmes-Weinstein monofilament test results were reported for 6 individuals. Two of the 6 individuals had a grade of 5 (normal sensation) at their latest follow-up. Two individuals had diminished light sensation, and a grade of 4. Two individuals had an absence of protective sensation or non-testable sensation. Nine of 10 individuals experienced at least 1 episode of rejection, with a range of 1 to 38 acute rejection episodes per person. Four of 10 had episodes of grade II-IV histologic rejection and 1 individual experienced graft failure 5 days after transplantation.

A study comparing outcomes after hand transplantation and prosthetics in individuals with below-elbow amputation was published in 2016 by Salminger and colleagues. The study included 12 individuals, 5 of which had hand transplantation and 7 of which had prosthetics. Two hand transplantation recipients had bilateral procedures and hence 7 hand transplants were compared with 7 prosthetic hands. Several types of myoelectric prosthetics with simple direct control were used, depending on the individual's exact level of amputation. Functional outcome measures included the DASH, the Action Research Arm Test (ARAT), maximum score of 57 points, and the Southampton Hand Assessment Procedure (SHAP), maximum score of

100 points indicating normal hand function. The mean DASH score was 22.5 (standard deviation [SD], 19.7) in transplanted hands and 10.8 (SD, 6.4) in prosthetic hands; scores did not differ significantly between groups, p=0.40. The mean ARAT scores were 40.9 (SD, 8.1) in the transplanted hands and 39.0 (SD, 3.6) in the prosthetic hands, with a non-significant between-group difference, p=0.87. The SHAP scores also did not differ significantly between groups (p=0.98); mean scores were 75.0 (SD, 11.1) in the transplanted hands and 75.4 (SD, 10.8) in the prosthetic hands. The SF-36 Health Survey (SF-36), which is sub-divided into eight scales, four for physical health and four for mental health, was used to measure quality of life; each scale is scored with a maximum of 100 points. The authors did not report an overall SF-36 score. Three of four physical health scales (physical functioning, bodily pain and general health) did not differ significantly between groups and the fourth (role-physical) favored the hand transplant group. Three of the four mental health scales, vitality, role-emotional, and mental health, but not social functioning, were significantly higher in the hand transplantation group compared with the prosthetics group.

In 2013, the American Society for Surgery of the Hand (ASSH) Council published the following statement on hand transplantation:

> **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.**

To date, only a small number of individuals worldwide and in the United States have undergone hand transplantation. Although hand transplants can improve function, the available data suggest that functional outcomes may not be significantly better than with hand prosthetics. Moreover, there are potential adverse events associated specifically with hand transplantation, and a substantial proportion of hand transplants have been amputated. In conclusion, the data are insufficient that hand transplantation improves the net health outcome.

Background/Overview

Hand transplantation is a type of VCA transplantation. In the United States, in 2014 VCAs were added to the list of OPTN oversight. Prior to 2014, VCA was known as composite tissue allotransplantation (Hein, 2020). The OPTN /United Network for Organ Sharing (UNOS) (Hernandez, 2022) defines a VCA transplant as replacement of a body part that meets the following criteria:

- **Is vascularized and requires blood flow by surgical connection of blood vessels to function after transplant**
- **Contains multiple tissue types**
- **Recovered from a human donor as an anatomic/structural unit**
- **Surgically implanted in a human recipient as an anatomic/structural unit**
- **Minimally manipulated (ie, processing that does not alter the original relevant characteristics of the organ relating to its utility for reconstruction, repair, or replacement)**
- **For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic functions in the recipient as in the donor)**
- **Not combined with another article such as a device**
- **Susceptible to ischemia and, therefore, stored only temporarily and without cryopreservation**
- **Susceptible to allograft rejection**

The first successful hand transplant was performed in 1998 and, since that time, between 100 and 200 procedures have been performed worldwide, with approximately 30 of these done in the United States. There have also been at least 24 amputations of transplanted hands due to factors such as bacterial infection, multiple rejection episodes or arterial ischemia (Lúcio, 2021).

Hand transplantation is an alternative to use of hand prosthetic fitting, and both interventions have potential benefits and risks. Unlike with prosthetics, with transplantation, individuals have a chance of sensory recovery and recovery of fine motor movement. Moreover, hand transplantation can have psychological benefits such as a sense of wholesomeness and bodily integrity. However, hand transplant recipients require ongoing rehabilitation and lifelong treatment with immunosuppressive drugs. Possible adverse effects include acute and chronic rejection, infection, neoplasia, metabolic disorders, and organ failure. Prosthetic hand technology has advanced and myelectric prostheses (see CG-OR-PR-05 Myoelectric Upper Extremity Prosthetic Devices), which are controlled by electromyographic (EMG) signals generated naturally by an individual's own muscles, can substantially replace motor function. Hand prosthetics also have the

advantages of not needing lifelong medication, and they can be fit shortly after the injury and do not require additional surgeries. Disadvantages include the lack of sensory information which makes it difficult to perform precise motor tasks, which might lead the individual to abandon the prosthetic device.

Definitions

Allogeneic transplantation: The transplantation of cells, tissues, or organs to an individual from a donor who is not genetically identical (e.g. not an identical twin).

Myoelectric: Electric signals that stimulate muscles to move. These electrical impulses can be amplified and used to control artificial limbs.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
26989	Unlisted procedure, hands or fingers [if specified as allogeneic transplantation of hand]

ICD-10 Procedure	
0XYJ0Z0	Transplantation of right hand, allogeneic, open approach
0XYJ0Z1	Transplantation of right hand, syngeneic, open approach
0XYK0Z0	Transplantation of left hand, allogeneic, open approach
0XYK0Z1	Transplantation of left hand, syngeneic, open approach

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Hein RE, Ruch DS, Klifto CS et al. Hand transplantation in the United States: A review of the Organ Procurement and Transplantation Network/United Network for Organ Sharing Database. Am J Transplant. 2020; 20(5):1417-1423.
2. Lúcio MJ, Horta R. Hand transplantation-risks and benefits. J Hand Microsurg. 2020; 13(4):207-215.
3. Salminger S, Sturma A, Roche AD et al. Functional and psychosocial outcomes of hand transplantation compared with prosthetic fitting in below-elbow amputees: A multicenter cohort study. PLoS One. 2016; 11(9):e0162507.
4. Wells MW, Rampazzo A, Papay F, Gharb BB. Two decades of hand transplantation: A systematic review of outcomes. Ann Plast Surg. 2022; 88(3):335-344.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Society for Surgery of the Hand Council. ASSH position statement on hand transplantation 2013. J Hand Surg Am. 2013; 38(11):2234-5.
2. Hernandez JA, Miller J, Oleck NC et al. OPTN/SRTR 2020 annual data report: VCA. Am J Transplant. 2022; 22 Suppl 2:623-647.

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Vascularized composite allograft

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action

New	**08/11/2022**	**Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.**

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.