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MEDICAL POLICY – 7.03.13

Composite Tissue Allotransplantation of the Hand and Face

BCBSA Ref. Policy:	7.03.13	
Effective Date:	Nov. 1, 2026	RELATED MEDICAL POLICIES:
Last Revised:	Oct. 26, 2026	None
Replaces:	N/A	

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Introduction

A face or hand transplant involves transferring many different types of tissue such as bone, blood vessels, muscle, nerve tissue, and skin from one person to another. The donor's family is consulted and the tissue is gathered only after the family agrees that their loved one's tissues may be used in this way. Because this surgery is so extensive and involves many different types of tissue, the risks are considered to be high. While these surgeries have been done, they have only been done on a very small number of people. There is not enough medical evidence to determine if the benefits to an individual outweigh the risk of complications, infections, tissue rejection, and problems with the immune system from long-term use of anti-rejection drugs. For these reasons, face and hand transplants are considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Composite tissue allotransplantation, hand and/or face	**Composite tissue allotransplantation of the hand and/or face is considered investigational.**

Coding

Currently, there are no specific CPT codes for this procedure.

Related Information

N/A

Evidence Review

Description

Composite tissue allotransplantation (also referred to as vascularized composite allotransplantation) is defined as transplantation of histologically different tissues. This type of transplantation is being proposed for facial transplants in individuals with severely disfigured faces, and for hand transplants in individuals dissatisfied with prosthetic hands. The treatment has potential benefits in terms of improving functional status and psychosocial well-being. It also has potential risks, most notably those associated with a lifelong regimen of immunosuppressive drugs.

Background

Composite Tissue Allotransplantation

Composite tissue allotransplantation refers to the transplantation of histologically different tissue that may include skin, connective tissue, blood vessels, muscle, bone, and nerve tissue. The procedure is also known as reconstructive transplantation. To date, primary applications of this type of transplantation have been of the hand and face (partial and full), although there are also reported cases of several other composite tissue allotransplantations, including that of the larynx, knee, and abdominal wall.

Hand and face transplants have been shown to be technically feasible. The first successful partial face transplant was performed in France in 2005, and the first complete facial transplant was performed in Spain in 2010. In the United States, the first facial transplant was done in 2008; it was a near-total face transplant and included the midface, nose, and bone. The first hand transplant with short-term success occurred in 1998 in France. However, the individual failed to follow the immunosuppressive regimen, which led to graft failure and removal of the hand 29 months after transplantation. The firsthand transplantation in the United States took place in 1999.

Composite tissue allotransplantation procedures are complex and involve a series of operations using a rotating team of specialists. For face transplantation, the surgery may last eight to 15 hours. Hand transplant surgery typically lasts between eight and 12 hours. Bone fixation occurs first, and this is generally followed by the artery and venous repair and then by suture of nerves and/or tendons. In all surgeries performed to date, the median and ulnar nerves were repaired. The radial nerve was reconstructed in about half of the procedures.

Unlike most solid organ transplantations (e.g., kidney and heart transplants), composite tissue allotransplantation is not life-saving, and its primary aim rests mainly in an individual's cosmetic satisfaction and quality of life. In the case of facial transplantations, there is immense potential for the psychosocial benefits when a surgery is successful. Moreover, the goal of composite tissue transplantation is to improve function (e.g., grasping and lifting after hand transplants, blinking and mouth closure after face transplants) without alternative interventions such as prosthetics. Additionally, in the case of face transplantation, the procedure may be less traumatic than "traditional" facial reconstructive surgery using the individual's own tissue. For example, traditional procedures often involve dozens of operations, whereas facial transplantation involves only a few operations.

Adverse Events

Composite tissue allotransplantation is associated with potential risks and benefits, and individuals who undergo face or hand transplantation must adhere to a lifelong regimen of immunosuppressive drugs. Risks of immunosuppression include acute and chronic rejection, an opportunistic infection that may be life-threatening, and metabolic disorders such as diabetes, kidney damage, and lymphoma. A review of 115 facial or upper extremity transplants found an overall acute rejection rate of 89% with 11% of recipients with chronic rejection.[1] Other challenges include the need to participate actively in intensive physical therapy to restore functionality and the potential for frustration and disappointment if functional improvement does not meet expectations. Moreover, there is the potential for allograft loss, which would lead to additional procedures in hand transplant individuals, and there are limited reconstructive options for facial transplantation. Furthermore, in the case of hand transplants, there is a risk that functional ability (e.g., grasping and lifting objects) may be lower than with a prosthetic hand, especially compared with newer electronic prosthetic devices. Due to the importance of selecting candidates who can withstand these physical and mental challenges, potential hand and face transplant recipients undergo extensive screening for both medical and psychosocial suitability.

Summary of Evidence

For individuals who have a severely disfigured face due to burns or trauma who receive composite tissue allotransplantation, the evidence includes a small case series and several systematic reviews of case series. The relevant outcomes are functional outcomes, quality of life, resource utilization, and treatment-related mortality and morbidity. The available studies on composite tissue allotransplantation of the face have suggested that the surgery is technically feasible; however, to date, only a limited number of individuals worldwide have undergone the procedure, and the data are not sufficiently robust to determine whether the potential benefits to individuals outweigh the potential risks (e.g., of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had hand and upper-extremity amputation(s) who receive composite tissue allotransplantation, the evidence includes a small case series, several systematic reviews of case series, and a nonrandomized comparative study. The relevant outcomes are functional outcomes, quality of life, resource utilization, and treatment-related mortality and morbidity. The available studies on composite tissue allotransplantation of the hand have suggested that the surgery is technically feasible. The only study comparing outcomes in individuals who had hand

transplants with those who received prostheses included 12 individuals. It found no differences between groups in functional outcomes and little difference in quality of life. Given the limited number of individuals worldwide who have undergone the procedure and the limited amount of data comparing outcomes with the best available prosthetics, the evidence is not sufficiently robust to determine whether the potential benefits to individuals outweigh the potential risks (e.g., of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing clinical trial that might influence this review is listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01459107	Human Upper Extremity Allotransplantation	30	Jun 2036 (recruiting)

NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

International Consensus Recommendations

A 2021 modified Delphi process with 35 international transplant stakeholders developed 52 recommendations for face transplants.[11] Areas addressed included patient assessment and selection, indications, social support networks, clinical framework, surgical considerations, data on patient progress and outcomes, definitions of success and failure, public image and perception, and financial sustainability. The consensus group reported the need for standardized protocols in candidate assessment and selection, a formalized process for timely reporting and sharing of outcomes, a consensus definition of failure, and a need for financial funding systems. They recommended the following as indications for face transplant:

- "Face transplantation is indicated for the treatment of extended craniofacial defects and defects involving mid and central aesthetic facial units.
- Face transplantation might be considered as a first-line approach, following a thorough benefit vs risk evaluation, for craniofacial defects involving key anatomical and functional structures and/or so extensive to predict a suboptimal outcome of conventional reconstruction.
- Face transplantation is indicated for defects with a complete loss of the orbicularis oculi and/or orbicularis oris muscles.
- A past medical history of benign tumor should not be considered as a contraindication to face transplantation."

National Institute for Health and Care Excellence

In 2011, the NICE published guidance on hand allotransplantation.[12] The guidance stated that the quantity of current evidence on the efficacy and safety of hand allotransplantation was inadequate.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Hand and face allotransplantations are surgical procedures and, as such, are not subject to regulation by the US Food and Drug Administration.

References

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12. National Institute for Health and Care Excellence (NICE). Hand allotransplantation [HTG254]. 2011; **https://www.nice.org.uk/guidance/HTG254**. Accessed October 6, 2026.

History

Date	Comments
04/08/13	New Policy. Policy created with literature review through January 14, 2013. Considered investigational.
05/05/14	Annual Review. Policy updated with literature review through January 3, 2014. References 2, 7, and 8 added. No change to policy statement. Add unlisted CPT codes 21499 & 21299. Change the title to Face and Hand Transplant using Composite Tissue Allotransplantation for clarification purposes.
04/24/15	Annual Review. Policy updated with literature review through January 7, 2015. References 2, 4-5, and 12 added. Policy statement unchanged.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through December 14, 2015; reference 2 added; others renumbered/removed. Policy statement unchanged.
10/01/17	Annual Review, approved September 21, 2017. Policy updated with literature review through June 22, 2017; references 2 and 7 added. Policy statement unchanged.
10/01/18	Annual Review, approved September 20, 2018. Policy updated with literature review through June 2018; no references added. Policy statement unchanged.
11/01/19	Annual Review, approved October 4, 2019. Policy updated with literature review through June 2019; no references added. Policy statement unchanged.
11/01/20	Annual Review, approved October 22, 2020. Policy updated with literature review through May, 2020; no references added. Policy statement unchanged.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through May 17, 2021; no references added. Policy statement unchanged.
11/01/22	Annual Review, approved October 24, 2022. Policy updated with literature review through May 16, 2022; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/01/23	Annual Review, approved September 25, 2023. Policy updated with literature review through June 12, 2023; references added. Policy statement unchanged.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through July 1, 2024; references added. Policy statement unchanged.
12/01/25	Annual Review, approved November 10, 2025. Policy updated with literature review through July 21, 2025; references added. Policy statement unchanged.
11/01/26	Annual Review, approved October 26, 2026. Policy updated with literature review through July 6, 2026; no references added. Policy statement unchanged. Streamlined introduction and coding note. Removed CPT codes 21299, 21499, and 26989.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review

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Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.