Corporate Medical Policy

Composite Allotransplantation of the Hand and Face

File Name: composite_allotransplantation_of_the_hand_and_face
Origination: 4/2013
Last Review: 8/2024

Description of Procedure or Service

Composite tissue allotransplantation (CTA) refers to the transplantation of histologically different tissue which 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 CTA have been hand and face (partial and full) transplantations, although there are also reported cases of several other CTAs, including transplantation of the larynx, knee and abdominal wall.

Hand and face transplants have been found to be technically feasible. According to the International Registry on Hand and Composite Tissue Allotransplantation (IRHCTT) website, as of January 2013, more than 50 patients worldwide have undergone technically successful hand transplants and 15 patients have had face transplants. The most commonly performed face transplant procedure has been to restore the lower two-thirds of facial structure, especially the perioral area (i.e., lips, cheeks and chin) and in some cases the forehead, eyelids and scalp.

Facial transplantation has been performed on patients whose faces have been disfigured by trauma, burns, disease or birth defects and who are unable to benefit from traditional surgical reconstruction. Hand transplantations have been done in patients who lost a hand due to trauma or life-saving interventions causing permanent injury to the hand. To date, hand transplants have not been performed for congenital anomalies or loss of a limb due to cancer.

CTA procedures are complex and involve a series of operations using a rotating team of specialists. For face transplantation, the surgery may last 8 to 15 hours. Hand transplant surgery typically lasts between 8 and 12 hours. In all hand transplants, bone fixation occurred first and this was generally followed by 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), CTA is not life-saving, and its primary aim is to increase a patient's quality of life e.g., by having a more normal appearance and a sense of wholeness. In the case of facial transplantations in particular, there is a large potential psychosocial benefit of successful surgery. Moreover, it is hoped that function (e.g., grasping and lifting after hand transplants and basic functions such as blinking and mouth closure after facial transplants) may be better following CTA than with alternative interventions. In addition, in the case of face transplantation, the procedure may be less traumatic than "traditional" facial reconstruction surgery using the patient's own tissue. For example, traditional procedures often involve dozens of operations, whereas, facial transplantation involves only a few operations.

CTA is associated with potential challenges and risks as well as potential benefits. Patients who undergo face or hand transplantation must adhere to a lifelong regimen of immunosuppressive drugs. Risks of immunosuppression include acute and chronic rejection, opportunistic infection that may be life-threatening and metabolic disorders such as diabetes, kidney damage and

lymphoma. There are also potential adverse impacts on quality of life including the need to commit to a lifetime immunosuppression regimen. Other challenges include the need to actively participate in intensive physical therapy in order to obtain functionality and the potential for frustration and disappointment if functionality does not meet expectations. Moreover, there is the potential for allograft loss, which would lead to additional procedures in hand transplant patients, and there are limited reconstructive options for facial transplantation patients. 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 to 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.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Composite allotransplantation of the hand and/or face is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Composite Transplantation of the Hand and Face is covered

Not Applicable

When Composite Transplantation of the Hand and Face is not covered

Composite allotransplantation of the hand and/or face is considered investigational.

Policy Guidelines

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. 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 patients worldwide have undergone the procedure, and the data are not sufficiently robust to determine whether the potential benefits to patients outweigh the potential risks (eg, of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have 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. 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 patients who had hand transplants with those who received prostheses

included 12 patients. It found no differences between groups in functional outcomes and little difference in the quality of life. Given the limited number of patients 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 patients outweigh the potential risks (eg, of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: There is no specific code for this service. The unlisted code 26989 may be used.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 2/14/13

International Registry on Hand and Composite Tissue Allotransplantation (IRHCTT). Retrieved from http://www.handregistry.com

National Institute for Health and Clinical Excellence (NICE). Hand Allotransplantation. Retrieved from: http://www.nice.org.uk/nicemedia/live/12988/53627/53627.pdf

American Society for Reconstructive Microsurgery (ASRM) and the American Society of Plastic Surgeons (ASPS). Facial Transplantation-ASRM/ASPS Guiding Principles. Retrieved from: http://www.microsurg.org/assets/1/13/ftGuidelines.pdf

Medical Director review 3/2013

Specialty Matched Consultant Advisory Panel review 9/2013

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U.S. National Institutes of Health. Clinical Trials: Allogeneic Hand Transplantation Composite Tissue Allotransplantation. NCT00711373.

U.S. National Institutes of Health. Clinical Trials: Hand Transplantation for Treatment of Dominant
Hand or Bilateral Hand Amputees NCT01293214

U.S. National Institutes of Health. Clinical Trials: Face Transplantation (NCT01140087).

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 2/13/14

Specialty Matched Consultant Advisory Panel review 9/2014

Medical Director review 9/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 2/12/15

Specialty Matched Consultant Advisory Panel review 9/2015

Medical Director review 9/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 2/11/16

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 8/10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 8/9/18

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 8/8/19

Specialty Matched Consultant Advisory Panel 8/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.13, 9/2020

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National Institute for Health and Care Excellence (NICE). Hand allotransplantation [IPG383]. 2011; https://www.nice.org.uk/guidance/ipg383

American Society for Reconstructive Microsurgery (ASRM), American Society of Plastic Surgeons (ASPS). Facial Transplantation-ASRM/ASPS Guiding Principles. n.d.; http://www.microsurg.org/assets/1/13/ftGuidelines.pdf

Specialty Matched Consultant Advisory Panel 8/2022

Medical Director review 8/2022

Specialty Matched Consultant Advisory Panel 8/2023

Medical Director review 8/2023

Specialty Matched Consultant Advisory Panel 8/2024

Medical Director review 8/2024

Policy Implementation/Update Information

4/1/13	New policy developed. Composite allotransplantation of the hand and/or face is investigational. Medical Director review 3/2013. (mco)
10/15/13	Specialty Matched Consultant Advisory Panel review 9/2013. Medical Director review 9/2013. (mco)
4/1/14	Policy Guidelines updated to include clinical trial information. References updated. No changes to Policy Statement. (mco)
10/14/14	Specialty Matched Consultant Advisory Panel review 9/2014. Medical Director review 9/2014. (mco) (td)

3/31/15	References updated. Policy Statement unchanged. (td)
10/30/15	Specialty Matched Consultant Advisory Panel review 9/30/2015. Medical Director review 9/2015. (td)
10/25/16	Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 9/28/2016. No change to policy statement. (an)
9/15/17	Policy Guidelines updated. Reference added. Specialty Matched Consultant Advisory Panel review 8/30/2017. No change to policy statement. (an)
9/7/18	Specialty Matched Consultant Advisory Panel review 8/22/2018. No change to policy statement. (an)
9/10/19	Specialty Matched Consultant Advisory Panel 8/20/2019. Policy guidelines updated, no change to policy statement. (eel)
9/8/20	Specialty Matched Consultant Advisory Panel 8/19/2020. References updated. No change to policy statement. (eel)
9/7/21	References updated. Specialty Matched Consultant Advisory Panel 8/2021. Medical Director review 8/2021. (jd)
9/13/22	Minor updates in description section for clarity. References updated. Specialty Matched Consultant Advisory Panel 8/2022. Medical Director review 8/2022. (tt)
8/29/23	References updated. Specialty Matched Consultant Advisory Panel 8/2023. Medical Director review 8/2023. No change to policy statement. (tt)
9/18/24	References updated. Specialty Matched Consultant Advisory Panel 8/2024. Medical Director review 8/2024. No change to policy statement. (tt)