BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Composite Tissue Allotransplantation (CTA) of the Hand and Face

Policy #: 521
Category: Surgery
Latest Review Date: August 2020
Policy Grade: D

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on and after April 26, 2013:

Blue Advantage will treat **composite tissue allotransplantation (CTA) of the hand and/or face** as a **noncovered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Composite tissue allotransplantation 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 shown to be technically feasible. The first successful partial face transplant was performed in France in 2005. The first complete facial transplant was performed in Spain in 2010. In the United States, the first facial transplant was done in 2008; this 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 patient failed to follow the immunosuppressive regimen, which led to graft failure and removal of the hand 29 months after transplantation. The first hand transplantation in the United States took place in 1999.

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 may be better following CTA than with alternative interventions e.g., grasping and lifting after hand transplants and basic functions such as blinking and mouth closure after facial transplants. In addition, in the case of face transplantation, the procedure may be less traumatic than "traditional" facial reconstructive surgery using the patient's own tissue. For example, traditional procedures often involve dozens of operations whereas facial transplantation involves only a few operations.

Adverse Events
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.

KEY POINTS:
The policy was created in February 2013, with a current literature search of the MEDLINE database through May 22, 2020.

Summary of Evidence
For individual who have a severely disfigured face (e.g., burns, 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 sufficient to determine whether the potential benefits to patients outweigh the potential risks (e.g., of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individual 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 quality of life. Given the limited number of patients worldwide have undergone the procedure and the limited amount of data comparing outcomes with the best available prosthetics, evidence is insufficient to determine whether the potential benefits to patients outweigh the potential risks (e.g., of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American Society for Surgery of the Hand
In 2013, the American Society for Surgery of the Hand published a position statement on hand transplantation. The Society recognized that hand transplantation is an alternative to prostheses and rehabilitation in appropriately selected patients, yet the guidelines still considered hand transplantation an "innovative intervention." The statement emphasized the need for further advances in the areas of patient selection, surgical technique, and immunosuppression and recommended that, at this time, the procedure be carried out only in centers with extensive experience in both hand surgery and solid organ transplantation.

National Institute for Health and Care Excellence
In 2011, the National Institute for Health and Care Excellence published guidance on hand allotransplantation. The guidance stated that the quantity of current evidence on the efficacy and safety of hand allotransplantation is inadequate.

American Society for Reconstructive Microsurgery and American Society of Plastic Surgeons
In 2006, The American Society for Reconstructive Microsurgery (ASRM) and the American Society of Plastic Surgeons (ASPS) published guiding principles on facial transplantation for plastic surgeons. Selected principles are listed below:

"1. Facial transplantation should only be utilized for patients with severe facial deformities who cannot be helped through traditional reconstructive surgical measures.
2. Facial transplantation should only be undertaken in institutions with appropriate Institutional Review Boards familiar with the many intricacies for approval and application of new clinical procedures and protocols.
3. Facial transplantation should be conducted in the context of a transplant team having appropriate institutional resources and commitment to the project.
4. Appropriate patient selection criteria should be established and a complete risk/benefit ratio must be considered for each patient on a case-by-case basis.
5. To facilitate informed consent:
    - The physician must provide the patient with the latest and complete information on the risks associated with facial transplant.

- The preoperative evaluation of potential donors may involve additional considerations as more experience is gained. At this time the results of facial transplantation are unknown. If early results are less than optimal, potential patients should be informed of any newly identified limitation of the procedure.
- Patients must demonstrate a thorough understanding of all the known risks and benefits.
- The physician should regard the facial transplantation procedure as experimental and it should be subjected to the evaluation of an independent research ethics committee.
- The informed consent should include an alternative and acceptable solution for management of the recipients' face in the event of transplant failure… "

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Composite tissue allotransplantation (CTA), Vascularized composite tissue allotransplantation (VCA), Reconstructive transplantation (RT), Facial allograft transplantation, Hand allotransplantation

APPROVED BY GOVERNING BODIES:
Hand and face allotransplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes: No comparable CPT code exists for this procedure, so an unlisted procedure code is reported

21499	Unlisted musculoskeletal procedure, head
26989	Unlisted procedure, hands or fingers

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POLICY HISTORY:

Adopted for Blue Advantage, February 2013
Available for comment March 12 through April 25, 2013
Medical Policy Group, February 2014
Medical Policy Group, February 2015
Medical Policy Group, February 2016
Medical Policy Group, August 2017
Medical Policy Group, August 2018 **(3)**: Updates to Description and Key Points. No change in Policy Statement.
Medical Policy Group, September 2019
Medical Policy Group, August 2020