Medical Policy
Composite Tissue Allotransplantation of the Hand and Face

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Policy Number: 662
BCBSA Reference Number: 7.03.13
NCD/LCD: NA

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue\textsuperscript{SM} and Medicare PPO Blue\textsuperscript{SM} Members

Composite tissue allotransplantation of the hand and/or face is considered \textbf{INVESTIGATIONAL}.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<td>Medicare HMO Blue\textsuperscript{SM}</td>
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<tr>
<td>Medicare PPO Blue\textsuperscript{SM}</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes / ICD Codes
\textit{Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.}

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
CPT Codes
There are no specific CPT codes for this procedure.

ICD-9 Diagnosis Codes
Investigational for all diagnoses.

ICD-9 Procedure Codes
There are no specific ICD-9 procedure codes for this service.

Description
Composite tissue allotransplantation is defined as transplantation of histologically different tissues. This type of transplantation 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.

Background
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 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.

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 U.S., the first facial transplant was done in 2008 at the Cleveland Clinic; 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 U.S. took place in Louisville, KY in 1999.

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 transplants1. 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 scalp2.

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, composite tissue allotransplantation 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 composite tissue transplantation 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.

Composite tissue allotransplantation 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.

**Summary**
Composite tissue allotransplantation involves transplantation of histologically different tissues. Preliminary experience with composite tissue allotransplantation of the hand and face suggest that the surgery is technically feasible. To date, however, only a limited number of patients worldwide have undergone such allotransplantation of the hand and/or face. There are insufficient data on whether the procedure improves the net health outcome, i.e., whether the potential benefits to patient’s quality of life outweigh the potential risks, e.g., of surgical complications, immunosuppression and opportunistic infections. In addition, for hand transplantation, no published data are available comparing functional and quality-of-life outcomes compared to use of lower limb prostheses Thus, composite tissue allotransplantation of the hand and/or face is considered investigational.

**Policy History**

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<th>Date</th>
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<td>9/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<td>3/2015</td>
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<tr>
<td>8/2013</td>
<td>BCBSA National medical policy.</td>
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<td>New investigational indications described. Effective 8/1/2013.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**
Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**