Composite Tissue Allotransplantation of the Hand and Face

Number 7.03.13  
Effective Date August 1, 2016  
Revision Date(s) 07/12/16; 04/24/15; 05/05/14; 04/08/13  
Replaces N/A

Policy

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

Related Policies

None

Policy Guidelines

There are no specific CPT codes for the composite tissue allotransplantation procedure. It would be reported using combinations of existing codes or the unlisted code for the anatomic area. See the coding table below for possible code options.

Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tr>
<td>21299</td>
<td>Unlisted craniofacial and maxillofacial procedure</td>
</tr>
<tr>
<td>21499</td>
<td>Unlisted musculoskeletal procedure, head</td>
</tr>
<tr>
<td>26989</td>
<td>Unlisted procedure, hands or fingers</td>
</tr>
</tbody>
</table>

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 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 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, and the first complete facial transplant was performed in Spain in 2010. In the United States, 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 United States took place in Louisville, Kentucky, in 1999.

Hand and face transplants have been found to be technically feasible. 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, chin) and in some cases the forehead, eyelids and scalp. (1) 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 that caused permanent injury to the hand. To date, hand transplants have not been performed for congenital anomalies or loss of a limb due to cancer.

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 8 to 15 hours. Hand transplant surgery has typically lasted between 8 and 12 hours. 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 grasping and lifting after hand transplants and blinking and mouth closure after face transplants, may be better after composite tissue transplantation than with alternative interventions. Additionally, 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 the immunosuppression regimen. Other challenges include the need to actively participate in intensive physical therapy 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 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.

**Regulatory Status**

Hand and face allotransplantations are surgical procedures and not subject to regulation by the U.S. Food and Drug Administration (FDA).
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.

Benefit Application

Composite tissue allotransplantation surgery is offered at specialized centers. Locations offering this procedure include but may not be limited to:

- Brigham and Women’s Hospital
- Cleveland Clinic
- Duke University
- Jewish Hospital Hand Care Center (in partnership with Kleinert Kutz & Associates and the University of Louisville, in Kentucky)
- Johns Hopkins School of Medicine
- MD Anderson Cancer Center’s Department of Plastic Surgery
- University Medical Center at the University of Arizona
- University of California at Los Angeles (UCLA)
- University of Pittsburgh McGowan Institute for Regenerative Medicine

Rationale

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
  - With severely disfigured face due to, eg, burns or trauma | Interventions of interest are:  
  - Composite tissue allotransplantation of the face | Comparators of interest are:  
  - Standard care without facial allotransplantation | Relevant outcomes include:  
  - Functional outcomes  
  - Quality of life  
  - Resource utilization  
  - Treatment-related mortality  
  - Treatment-related morbidity |
| Individuals:  
  - With hand amputation(s) | Interventions of interest are:  
  - Composite tissue allotransplantation of the hand | Comparators of interest are:  
  - Standard care without hand allotransplantation (eg, hand prosthesis) | Relevant outcomes include:  
  - Functional outcomes  
  - Quality of life  
  - Resource utilization  
  - Treatment-related mortality  
  - Treatment-related morbidity |

This evidence review was created in February 2013 with a search of the MEDLINE database through January 14, 2013. This evidence report has been updated regularly the most recent literature review is through December, 2015. Following is a summary of the key literature to date.

Face Allotransplantation

As of December 2015, a total of 31 face allotransplantation operations have been conducted. (2) The most recent systematic analysis of outcomes was published in 2014 by Smeets et al. (3) The authors included English
language articles published through September 15, 2013, that provided data on at least 1 face transplant in humans. A total of 36 articles reported on 27 worldwide face transplantations. University Hospital Henri Mondor in Creteil, France, and Brigham and Women’s Hospital in Boston, Massachusetts, were the centers with the most experience. Ten of the 27 cases were full face transplants (the first successful full face transplant was in 2010) and the remainder were partial face transplants. The literature did not report any case of graft loss, hyperacute (within the first 48 hours) or chronic rejection, or graft-versus-host disease. However, all of the face transplant recipients with at least 1-year postsurgical follow-up were reported to experience at least 1 episode of acute rejection days or months after the procedure. Other common complications were related to drug toxicity from immunosuppressive therapy, leading to opportunistic infections, metabolic disorders, and increased incidence of malignancy. There have been 3 reported cases of malignancy to date. Three deaths occurred in transplant recipients. One patient died 27 months after surgery due to lack of compliance with immunosuppressive therapy. A second death occurred in a French recipient who had multidrug-resistant infection and graft necrosis (an early transplant in France). The third patient died of recurrent cancer.

In terms of function, tactile sensitivity recovered a mean of 4.1 months after surgery when nerve repair was performed, and a mean of 7.3 months otherwise. Temperature sensitivity recovered a mean of 4.3 months with nerve repair and 12.5 months without nerve repair. Motor recovery began a mean of 7.8 months after surgery. Recovery of motor function has started with contractions of single muscles, and complex movements have appeared within the first year in a number of patients. Long-term results are still pending in most cases. After 5 years of follow-up, the first face transplant recipient was able to fully open her mouth, smile, speak, chew, and swallow.

Also in 2015, Fischer et al. identified a total of 29 face transplants performed through December 2013 and reported functional outcomes in 5 patients treated at their center. (4) The investigators compared each patient’s pre- and postsurgical functioning on various dimensions. Before surgery, all 5 patients had compromised respiration, breathing, sensation, and facial expression. After surgery, they had substantial recovery in all of these areas. In terms of breathing, the 5 patients were able to breathe through their noses postsurgery, and the 2 patients who previously had tracheostomy tubes had them removed. Speech became understandable to an unfamiliar listener 3 to 9 months after surgery. Three to 9 months postsurgery, most allografts were responsive to light touch, and patients could distinguish between heat and cold. Facial expression, including the ability to smile, recovered after transplantation in all patients. Three of 5 patients were unable to chew solid food before surgery, and 2 patients had liquid leakage. All patients were capable of oral food intake 3 to 29 days after surgery, and 3 to 12 months after surgery, all had unrestricted or nearly unrestricted eating and drinking. The 2 patients with compromised ability to smell both reported a substantial improvement in smelling, comparable with their functioning before facial trauma. All 5 patients developed opportunistic infections (viral or bacterial) after facial transplantation.

**Hand Allotransplantation**

The most comprehensive reporting of the worldwide experience with hand/upper limb transplant was published by Shores et al in 2015. (5) The authors identified 72 patients: 37 received bilateral transplants and 35 unilateral, for a total of 107 transplanted hand/upper extremities. There are 4 known mortalities: 1 occurred after a bilateral hand transplant, and the other 3 followed multitype composite tissue allotransplantations, CTAs (i.e., combined upper- and lower-limb or combined upper-limb and face transplants). Twenty-four graft losses have been reported; 8 of these were also associated with multiple CTA procedures and another 7 occurred in China during their early experience with hand transplantation. In the United States, 21 known patients have undergone isolated upper limb transplantation; 13 were unilateral and 8 were bilateral (limb or digit) procedures. There was 1 immediate graft loss of the bilateral transplanted limb/digit. An additional 3 patients experienced hand loss at approximately 9 months, 2 years, and 4 years post-transplant, respectively. Few data on functional outcomes after hand transplantation have been reported. The authors noted that there is a lack of agreement on appropriate outcome measures, and the level of transplantation varies greatly among patients, making it difficult to compare functional improvement.

An article describing data from the International Registry on Hand and Composite Tissue Allotransplantation was published in 2011. (6) At the time data were prepared for the article, hand transplants had been reported to the registry in a total of 39 patients. The article stated that 85% of transplant recipients experienced at least one episode of acute rejection in the first year after transplant. Acute rejection episodes were reversible in all patients who were compliant with treatment. The most commonly reported complications were metabolic complications (35/39 [90%]) and opportunistic infections (30/39 [77%]). Transient hyperglycemia occurred in 17 patients (44%) and cytomegalovirus reactivation in 10 patients (26%). Ten patients required surgery for complications (2 arterial
thrombosis, 1 venous thrombosis, 6 small area of skin necrosis, 1 venous fistula). Five cases of graft loss were reported between day 5 and day 275 after transplant. The early (day 5) graft loss occurred in a patient who underwent face and bilateral hand transplant, and this patient died at day 65 from cerebral anoxia. This was the only reported death in this series of patients. Hand function was reported in figures included in the article, but specific numbers e.g. mean function scores, were not included in the text of the article.

No studies comparing health outcomes in patients undergoing hand transplantation versus receiving hand/lower-limb prostheses were identified.

**Ongoing and Unpublished Clinical Trials**

Some ongoing clinical trials that might influence this review are listed in Table 1.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<tr>
<td>NCT01281267</td>
<td>Face Transplantation for Treatment of Severe Facial Deformity</td>
<td>10</td>
<td>Sep 2018</td>
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<tr>
<td>NCT00722280</td>
<td>Human Upper Extremity (hand and forearm) Allotransplantation</td>
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<td>Jan 2019</td>
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<td>NCT01459107</td>
<td>Human Upper Extremity Allotransplantation</td>
<td>30</td>
<td>Jun 2021</td>
</tr>
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</table>

NCT: national clinical trial.

**Summary of Evidence**

The evidence for composite tissue allotransplantation in individuals who have a severely disfigured face due to, (eg, burns or trauma) includes small case series and 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 suggest that the surgery is technically feasible. To date, however, only a limited number of patients worldwide have undergone the procedure and data are not sufficient 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.

The evidence for composite tissue allotransplantation in individuals who have hand amputation(s) includes small case series and 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 suggest that the surgery is technically feasible. To date, however, only a limited number of patients worldwide have undergone the procedure and data are not sufficient to determine whether the potential benefits to patients outweigh the potential risks (eg, of surgical complications, immunosuppression, opportunistic infections). In addition, no published data are available assessing functional and quality-of-life outcomes compared with use of lower-limb prostheses. 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 November 2013, the American Society for Surgery of the Hand published a position statement on hand transplantation. (7) The organization recognized that hand transplantation is an alternative to prostheses and rehabilitation in appropriately selected patients yet continued to consider it 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 Clinical Excellence (NICE)**

In March 2011, the National Institute for Health and Clinical Excellence (NICE) in the U.K. published guidance on hand allotransplantation. (8) The guidance stated that current evidence on the efficacy and safety of hand allotransplantation is inadequate in quantity. NICE recommended that the procedure only be available under special arrangements, e.g., in a research setting.
American Society for Reconstructive Microsurgery and the American Society of Plastic Surgeons

In 2006, The American Society for Reconstructive Microsurgery and the American Society of Plastic Surgeons published guiding principles on facial transplantation for plastic surgeons. (9) Selected principles follow:

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:
   a. The physician must provide the patient with the latest and complete information on the risks associated with facial transplant.
   b. 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.
   c. Patients must demonstrate a thorough understanding of all the known risks and benefits.
   d. The physician should regard the facial transplantation procedure as experimental and it should be subjected to the evaluation of an independent research ethics committee.
   e. 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.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

9. American Society for Reconstructive Microsurgery (ASRM) and the American Society of Plastic Surgeons (ASPS). Facial Transplantation-ASRM/ASPS Guiding Principles. Available online at:
Appendix

N/A

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
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<td>04/08/13</td>
<td>New Policy. Policy created with literature review through January 14, 2013. Considered investigational.</td>
</tr>
<tr>
<td>05/05/14</td>
<td>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 &amp; 21299. Change the title to Face and Hand Transplant using Composite Tissue Allotransplantation for clarification purposes.</td>
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<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. Policy updated with literature review through December 14, 2015; reference 2 added; others renumbered/removed. Policy statement unchanged.</td>
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Email AppealsDeportmentInquines@Premera.com

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https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

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Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog kog daim ntawv thov kev pas lus yog kog qhov kev pas cbam laos ntawv Premera Blue Cross. Tej zaum muaj cov hnb txog ceeb lus pas daim ntawv no. Tej zaum kog daim ntawv tshaj kev pas daim pas kog tshay kev passes daim pas kog daim ntawv lus pas daim kog tshay kev passes daim pas kog daim ntawv no. Tej zaum kog daim ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb lus pas daim ntawv no. Tej zaum kog daim ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb lus pas daim ntawv no. Tej zaum kog daim ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb lus pas daim ntawv no. Tej zaum kog daim ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb lus pas daim ntawv no. Tej zaum kog daim ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb lus pas daim ntawv no. Tej zaum kog daim ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb lus pas daim ntawv no.
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