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. Face or hand transplant surgeries often last many hours. A face transplant takes at least 12 hours and may last up to 36 hours. A hand transplant takes between 8 to 15 hours. (By comparison, a heart transplant usually takes between 6 and 8 hours.) 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 a patient 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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite tissue allotransplantation, hand and/or face</td>
<td>Composite tissue allotransplantation of the hand and/or face is considered investigational.</td>
</tr>
</tbody>
</table>

Coding

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<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>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

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 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

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.

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 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.

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. 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 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 (eg, kidney and heart transplants), composite tissue allotransplantation is not life-saving, and its primary aim rests mainly in a patient’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, that the goal of composite tissue transplantation is to improve function (eg, 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 patient’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 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. 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 patients, and there are limited reconstructive options for facial transplantation. Furthermore, in the case of hand transplants, there is a risk that functional ability (eg, 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. 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 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. 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 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.

Ongoing and Unpublished Clinical Trials

Some ongoing clinical trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01281267</td>
<td>Face Transplantation for Treatment of Severe Facial Deformity</td>
<td>10</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT01459107</td>
<td>Human Upper Extremity Allotransplantation</td>
<td>30</td>
<td>Jun 2026</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00722280</td>
<td>Human Upper Extremity (hand and forearm) Allotransplantation</td>
<td>300</td>
<td>Jan 2018 (terminated)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

**American Society for Surgery of the Hand**

The American Society for Surgery of the Hand (2013) 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**

The National Institute for Health and Care Excellence (2011) published guidance on hand allotransplantation. The guidance stated that the quantity of current evidence on the efficacy and safety of hand allotransplantation was inadequate.
American Society for Reconstructive Microsurgery and American Society of Plastic Surgeons

The American Society for Reconstructive Microsurgery and the American Society of Plastic Surgeons (2006) published guiding principles on facial transplantation for plastic surgeons. 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.”

Medicare National Coverage

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

Regulatory Status

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

References


```
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
</tbody>
</table>
```
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 and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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.
Discrimination is Against the Law

LifeWise Health Plan of Washington complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

LifeWise:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
• Qualified sign language interpreters
• Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
• Qualified interpreters
• Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at 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

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through LifeWise Health Plan of Washington. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-592-6804 (TTY: 800-842-5357).

Français (French):

Deutsche (German):

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過LifeWise Health Plan of Washington提出的申請或保障的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-592-6804 (TTY: 800-842-5357).

Oromoo (Cushite):

Kreyòl ayisyén (Creole):

Hmoo (Hmong):
Tsaab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb. Tjaa zaun tsaab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb baa muaj kajt ntawv thov kev pab yoy kajt thov kev pab yoy kajt xam muaj cov tseem cov caij nyoog uas teev tseg rau hauv daim ntawv no. Tej zaun kajt kajt yuav tau uas qee yam uas peb kom kajt kev tshiis pub duau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas kajt kev tshiis pub duau cov caij nyoog uas teev tseg rau hauv daim ntawv no. Tjaa zaun cov hnuub tseem cov caij nyoog tau uas rau hauv daim ntawv no. Tej zaun kajt kajt yuav tau uas qee yam uas peb kom kajt kev tshiis pub duau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas kajt kev tshiis pub duau cov caij nyoog uas teev tseg rau hauv daim ntawv no. Kajt muaj caij laww muab cov ntsiab lus no uas tau muab sau uas kom hnuub pub dawb rau kajt. Hu rau 800-592-6804 (TTY: 800-842-5357).

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggip iti aplikasyon w enwo coverage babaen iti LifeWise Health Plan of Washington. Daytoy a pakdaar mabalin nga adanan nga aramideny nga adda sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-ayto wенwo kasadagad tagasit. Addas karbenganyo a mangala iti daytoy nga impormasion ken tungo ti yuqodo a pagasao nga awan ti bayadanyo. Tumawag iti numero nga 800-592-6804 (TTY: 800-842-5357).