FEP 7.03.13 Composite Allotransplantation of the Hand and Face

Effective Date: January 15, 2019
Related Policies: None

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 dissatisfied 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.

Composite tissue allotransplantation refers to the transplantation of histologically different tissue that 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 (ie, 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 transplantsations 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 typically lasts 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 transplants (e.g., 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 transplants, there is immense potential for the psychosocial benefits when a surgery is successful. Moreover, the goal of composite tissue transplantation is to improve function (e.g., 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 only involves 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 (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.

**OBJECTIVE**
The objective of this evidence review is to determine whether composite tissue allotransplantation of the hand and/or face improves the net health outcome compared with standard management without transplantation.

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

**BENEFIT APPLICATION**
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA 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.

**RATIONALE**

**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 (e.g., of surgical complications,
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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.

SUPPLEMENTAL INFORMATION

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.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Effective Policy Date: January 15, 2019

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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


POLICY HISTORY

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2013</td>
<td>New Policy</td>
<td>Policy updated with literature review. References 2, 7, and 8 added. No change to policy statements.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review. References 2, 7, and 8 added. No change to policy statements.</td>
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<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through June 22, 2017; references 2 and 7 added. Policy statement unchanged.</td>
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<tr>
<td>December 2018</td>
<td>Update Policy</td>
<td>Policy updated with literature review through June 7, 2018; no references added. Policy statement unchanged.</td>
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