



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 03/19/13
LAST REVIEW DATE: 03/04/14
LAST CRITERIA REVISION DATE:
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COMPOSITE TISSUE ALLOTRANSPLANTATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Composite tissue allotransplantation (CTA) is transplantation of histologically different tissues. It has been investigated for facial transplants in individuals with severely disfigured faces and for hand transplants in individuals unsatisfied with prosthetic hands.

Unlike most solid organ transplantations (e.g., kidney and heart transplants), CTA is not life-saving and, its primary aim is to increase an individual'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 individual's own tissue. For example, traditional procedures often involve dozens of operations whereas facial transplantation involves only a few operations.

COMPOSITE TISSUE ALLOTRANSPLANTATION (cont.)

Description: (cont.)

CTA is associated with potential challenges and risks as well as potential benefits. Individuals 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 individuals, and there are limited reconstructive options for facial transplantation individuals. 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.

Criteria:

- Composite tissue allotransplantation of the face and/or hand is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome.
- Composite tissue allotransplantation of other body parts not listed above is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome.

These body parts include, *but are not limited to:*

- Ankle
- Foot
- Lower extremity
- Lower leg
- Thigh
- Toes



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COMPOSITE TISSUE ALLOTRANSPLANTATION (cont.)

Resources:

1. 7.03.13 BCBS Association Medical Policy Reference Manual. Composite Tissue Allotransplantation (CTA) of the Hand and Face. Re-issue date 02/13/2014, issue date 02/14/2013.