

List Covered Body Parts Pertaining to VCA

- Sponsoring Committee:** Vascularized Composite Allograft (VCA) Transplantation Committee
- Policy/Bylaws Affected:** OPTN Bylaws, Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs), Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs), Appendix M (Definitions), and OPTN Policy 1.2 (Definitions)
- Public Comment:** January 25, 2016 - March 25, 2016
- Effective Date:** To be determined; UNOS will notify members at least 30 days in advance of implementation.

Problem Statement

The OPTN Final Rule requires the Organ Procurement and Transplantation Network (OPTN) to implement policies related to vascularized composite allografts (VCAs) and identify all covered body parts in any policies specific to VCAs. Current OPTN Bylaws and Policies do not consistently specify these covered body parts. This proposal adds the list of covered body parts to include in OPTN Bylaws and Policies in order to meet the requirements of the Final Rule.

Summary of Changes

Changes to OPTN Bylaws and Policies include:

- Adding the list of eight Covered Body Parts that are VCAs to OPTN Policy 1.2
- Modifying training and experience requirements for the primary transplant surgeons of head and neck and upper limb transplant programs to make them consistent
- Making nonsubstantive changes to Bylaws, Appendix J for style, consistency, and clarity, including the general requirements for transplant hospitals applying for a VCA transplant program, multidisciplinary transplant exposure for the primary transplant surgeon for other VCA transplant programs, and the removal of the sunset provision of the experience pathway (in lieu of board certification) for the primary transplant surgeons of Upper Limb or Head and Neck transplant programs

What Members Need to Do

We will implement this proposal at the same time we make the changes to the membership requirements for VCA transplant programs that the Board approved in June of 2015. As a result of these changes and those that were approved in June 2015, VCA transplant programs will need to re-apply for OPTN/UNOS membership. When applying, the transplant program will have to identify its program type based on the list of covered body parts contained in this proposal in OPTN Policy 1.2.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

The following provisions of Appendix D do not apply to VCA transplant programs:

- ~~■ D.5: Transplant Program Director~~
- ~~■ D.6: Transplant Program Key Personnel~~
- ~~■ D.7: Changes in Key Transplant Program Personnel~~

D. Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HSS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program for at least one of the organ types involved in multi-visceral transplant. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. ~~In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.~~

Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval for each designated VCA transplant program.
- Completing a Personnel Change Application for a change in key personnel at each designated VCA transplant program.

For approval as a designated VCA transplant program, transplant hospitals must also:

1. Meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.
2. ~~Have current approval for and maintain a designated kidney, liver, heart, lung, or pancreas transplant program.~~ Have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

For more information on the application and review process, see *Appendix A: Membership Application and Review*.

J.3 Primary VCA Transplant Surgeon Requirements

Each designated VCA transplant program must have a primary transplant surgeon that meets *all* of the following requirements:

1. The primary surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The primary surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The primary surgeon must have documentation from the hospital's credentialing committee that it has verified the surgeon's state license, training, and continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The primary surgeon must have observed at least 2 multi-organ procurements.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in section J.3 above, the surgeon for an upper limb transplant program must meet both of the following:

1. Must meet at least *one* of the following:
 - a. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining *all* of the following relevant clinical experience: ~~as outlined below. As of September 1, 2018,~~

~~this pathway will no longer be available and all primary surgeons must meet the requirements of paragraph 1a.~~

- i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
- ii. Pre-operative evaluation of at least 3 potential upper limb transplant ~~patients~~ candidates.
- iii. Acted as primary surgeon of a least 1 upper limb transplant.
- iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

If a primary surgeon qualified under 1.b ~~ends his involvement with~~ leaves the transplant program, the replacement for this surgeon program must identify a primary transplant surgeon who meets the requirements under of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

2. Completion of at least *one* of the following:
 - a. ~~Completion of a~~ fellowship program in hand surgery that is approved by the MPSC. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program is automatically accepted by the MPSC.
 - b. ~~Completion of a~~ fellowship program in hand surgery that meets *all* of the following criteria will also be accepted:
 - i. The program is ~~located~~ at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - ii. The program is ~~located~~ at an institution that has a proven commitment to graduate medical education.
 - iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.
 - iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
 - v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
 - c. ~~The surgeon must have a~~ At least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon according to *Table J-1* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the

OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

Table J-1: Minimum Procedures for Upper Limb Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Bone	20
Nerve	20
Tendon	20
Skin or Wound Problems	14
Contracture or Joint Stiffness	10
Tumor	10
Microsurgical Procedures Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.3 above, the transplant surgeon for a head and neck transplant program must meet ~~at least one of~~ both of the following:

1. Must meet at least *one* of the following:
 - a. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining *all* of the following relevant clinical experience: ~~as outlined below. As of September 1, 2018, this pathway will no longer be available and all primary surgeons must meet the requirements of paragraph 1.a.~~
 - i. Observation of ~~e~~ at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
 - ii. Pre-operative evaluation of at least 3 potential head and neck transplant ~~patients~~ candidates.
 - iii. Acted as pPrimary surgeon of a least 1 head and neck transplant.
 - iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log

must be signed by the program director, division chief, or department chair where the experience was gained.

If a primary surgeon qualified under 1.b ~~ends his involvement with~~leaves the transplant program, the replacement for this surgeon program must identify a primary transplant surgeon who meets the requirements under of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

2. Completion of at least *one* of the following:
 - a. ~~Completion of a~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC. Any ACGME–approved fellowship program is automatically accepted by the MPSC.
 - b. ~~Completion of a~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets all of the following criteria:
 - i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - ii. The program is at an institution that has a proven commitment to graduate medical education.
 - iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery.
 - iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
 - v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
 - c. ~~The surgeon must have a~~At least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary surgeon or first-assistant, or a minimum number of head and neck procedures as the primary surgeon according to *Table J-2* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

Table J-2: Minimum Procedures for Head and Neck Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10

D. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA transplant program intending to transplant body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. The VCA transplant program must specify the body parts it will transplant in the application. In addition to the requirements as described in section J.3 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

1. ~~Specify the type or types of VCA transplant the surgeon will perform.~~

1. ~~2.~~ Have current American Board of Medical Specialties certification or the foreign equivalent in a specialty relevant to the type of covered body part the VCA transplant the surgeon will be performing.
2. ~~3.~~ Have gained all of the following relevant clinical experience ~~as outlined below~~:
 - a. Observation of at least 2 multi-organ procurements.
 - b. ~~Pre-operative~~ Participation in the multidisciplinary evaluations of at least 3 potential VCA transplant ~~patients~~ candidates.
3. ~~4.~~ Have at least 5 years of consecutive and independent practice of current working knowledge in the surgical specialty, ~~defined as independent practice in the specialty over a consecutive five-year period~~.
4. ~~5.~~ Have assembled a multidisciplinary surgical team that includes the primary surgeon with board certification in the relevant surgical specialty and other specialties ~~is~~ necessary to complete the VCA transplant ~~including, for example, such as~~ plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must also include a ~~team~~ member that has microvascular experience such as replantation, revascularization, free tissue transfer, ~~and or~~ major flap surgery. These procedures must be documented in a log that includes the dates of procedures, the role of the surgeon, and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. The team must have demonstrated detailed planning and cadaver rehearsals that are specific to the ~~type or types of covered body part the VCA transplant the program will perform~~.

A letter from the presiding ~~institutional~~ executive of the ~~institution~~ transplant hospital where the VCA transplant will be performed must provide written notification that requirements 1-~~5~~4 above have been met.

Appendix M: Definitions

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

For the list of covered body parts designated by the OPTN as VCAs, see Vascularized Composite Allograft (VCA) in OPTN Policy 1.2: Definitions.

OPTN Policies

1.2 Definitions

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

The following body parts are considered VCAs:

- Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap)
- Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx, parathyroid gland, scalp, trachea, or thyroid)
- Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements of the pelvis)
- Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder)
- Glands (including, but not limited to, adrenal or thymus)
- Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior lateral thigh flaps, or toe transfers)
- Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap)
- Spleen