

List Covered Body Parts Pertaining to Vascularized Composite Allografts (VCAs)

*VCA Transplantation Committee
June 6-7, 2016
Board of Directors Meeting*



How does this proposal support the OPTN Strategic Plan?

- Promote the efficient management of the OPTN
 - This proposal addresses an inconsistency between the OPTN Final Rule and OPTN Bylaws and Policies

What problem will the proposal solve?

- HRSA notified OPTN of inconsistency between OPTN Bylaws and Policies, and the Final Rule
- HRSA requested OPTN and VCA Committee generate list of covered body parts that are VCAs for purposes of the OPTN Bylaws and Policies
- VCA Committee drafted list of covered body parts, along with associated Bylaw and Policy changes



How was this proposal developed?

- VCA Committee collaborated with HRSA to create the list
- Intent was to create a list inclusive of current clinical practice and areas where advancement is reasonable
- One round of public comment (January to March 2016)
- Public comment outreach to five societies

List of Covered Body Parts

- **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**



Was this proposal changed in response to public comment?

- 17 comments submitted, 1 in opposition
- Changes made:
 - Non-substantive changes for style and clarity
 - Two minor modifications to the list of covered body parts
 - Added “Glands” to list
 - Clarified one example
 - Addressed an inconsistency between requirements of key personnel at upper limb, and head and neck transplant programs



How will members implement this proposal?

- Key personnel must meet qualifications in effect when they apply for approval
- When registering a VCA candidate, members must identify the specific covered body part they will transplant
- OPOs are highly encouraged to collaborate with VCA programs



How will the OPTN implement this proposal?

- Amend the formal membership application to reflect the new list of VCA types
- Review & approval of the membership application form by the U.S. Office of Management and Budget (OMB)
- UNOS systems that collect data on VCA candidates and transplants by VCA type will be modified
- Implementation – pending programming and notice to members

Overall Project Impact

Product Bylaw and policy modifications

Impacted Populations: *Current and future VCA transplant programs*

Total IT Implementation Hours 0/12,820

Total Overall Implementation and Maintenance Hours 605/19,560

Resolution 13 (page 65)

- RESOLVED, that the changes to OPTN Bylaws, Appendices D (Membership Requirements for 1 Transplant Hospital and Transplant Programs), J (Membership Requirements for Vascularized 2 Composite Allograft Transplant Programs), J.3 (Primary VCA Transplant Surgeon Requirements), M (Definitions), and OPTN Policy 1.2 (Definitions), as set forth below, are hereby approved, pending implementation and notice to OPTN members.
- FURTHER RESOLVED, that changes to OPTN Bylaws J.3.A (Additional Primary Surgeon Requirements for Upper Limb Transplant Programs) and J.3.B (Additional Primary Surgeon Requirements for Head and Neck Transplant Programs) are hereby approved, effective September 1, 2018.

Questions

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