

OPTN/UNOS Vascularized Composite Allograft Transplantation Committee

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

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

Executive Summary

The Organ Procurement and Transplantation Network (OPTN) Final Rule¹ requires the OPTN to implement policies related to VCAs and identify all covered body parts in any policies specific to VCAs. Current OPTN/UNOS Bylaws and Policies do not consistently specify these covered body parts. This proposal contains a list of covered body parts to include in OPTN/UNOS Bylaws and Policies in order to meet the requirements of the Final Rule.

The list of covered body parts is not an endorsement of research on a new type of organ transplant by the U.S. Department of Health and Human Services or the OPTN. The intent of these modifications is to make the OPTN/UNOS Bylaws and Policies consistent with the federal regulation, to provide transparency in what body parts are considered VCAs, and to define the scope of oversight by the OPTN.

¹ CFR §121.4(e)(3), <http://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5>

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

Affected Policies and Bylaws: OPTN/UNOS Bylaws Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs and Appendix M: Definitions; and OPTN/UNOS Policy 1.2: Definitions.

Sponsoring Committee: VCA Committee

Public Comment Period: January 25, 2015 to March 25, 2015

What problem will this proposal solve?

The OPTN Final Rule requires the OPTN to implement policies related to VCAs and to identify all covered body parts in any policies specific to VCAs². In July 2013, the Secretary of the Department of Health and Human Services (HHS) responded to comments received from the notice of potential rulemaking. Specifically, the Secretary noted that the OPTN would be required to list all covered body parts for transparency³. Current OPTN Bylaws and Policies do not consistently specify these covered body parts. Without specifying what body parts are VCAs, it is unclear what body parts are organs that fall under the auspices of the OPTN, compared to what body parts are included in the definition of human cells, tissues, and cellular and tissue-based products (HCT/Ps) governed by the U.S. Food and Drug Administration (FDA)⁴.

This proposal is not intended to address the source of VCAs, whether from deceased or living donors. For guidance on VCAs from living donors, see the Guidance Document on VCAs from Living Donors on the

² Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meets 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.

³ <https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurement-and-transplantation-network>

⁴ 42 U.S.C. 264 <http://api.fdsys.gov/link?collection=uscode&title=42&year=mostrecent§ion=264&type=usc&link-type=html>

OPTN website⁵. For guidance on deceased VCA donor authorization, see Guidance for Organ Procurement Organizations (OPOs) for VCA Deceased Donor Authorization on the OPTN website⁶.

Why should you support this proposal?

The proposal modifies OPTN/UNOS Bylaws and Policies to be consistent with federal regulation, to provide transparency in what body parts are VCA transplants, and define the scope of VCA oversight by the OPTN.

How was this proposal developed?

In July 2015, the Health Resources and Services Administration (HRSA) notified UNOS staff and VCA Committee (Committee) leadership of an inconsistency between the OPTN Final Rule and the OPTN Bylaws and Policies pertaining to VCAs, because current OPTN Bylaws and Policies do not consistently specify these covered body parts. HRSA subsequently directed the OPTN and the Committee to specify the covered body parts that fall under the purview of the OPTN.

The OPTN Final Rule provides the legal definition of VCA using nine criteria.⁷ The Committee considered the implications of a vascularized allograft meeting the nine criteria but not appearing on the list. HRSA explained that legally, a body part is a VCA, and thus an organ, if it meets the entire list of nine criteria in the Final Rule even if the OPTN/UNOS Bylaws and Policies do not include it on the list of VCAs covered by the Bylaws and Policies. Because body parts that meet the list of nine criteria are organs, they are governed by NOTA and the Final Rule. The absence of specific OPTN/UNOS Bylaws and Policies only affects whether the OPTN provides oversight over the specific VCA organ type.

The Committee was also concerned about the process and timeline required to modify the list of covered body parts in OPTN/UNOS Bylaws and Policies. Proposed changes to OPTN/UNOS Bylaws and Policies usually require a minimum of six to nine months for the Committee to diligently develop a proposal, distribute the proposed change for public comment, and to earn Board approval. The Committee was also concerned that this extended period could permit an emerging VCA transplant to occur without the knowledge of the OPTN, with no mechanism to collect data on the donation and outcome of the transplant, and the potential impact of a bad outcome on the entire field of VCA transplantation.

⁵ <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/>

⁶ https://optn.transplant.hrsa.gov/media/1137/vca_donor_guidance.pdf

⁷ http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_M

Vascularized Composite Allograft (VCA)

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

10. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
11. Containing multiple tissue types.
12. Recovered from a human donor as an anatomical/structural unit.
13. Transplanted into a human recipient as an anatomical/structural unit.
14. 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).
15. 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);
16. Not combined with another article such as a device.
17. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
18. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

The Committee, composed of members with subject matter expertise in the fields of transplant medicine and transplant and reconstructive surgery, developed the list based on clinical consensus, rather than statistical analysis. The Committee considered what vascularized allografts should appear on the list in light of the types of VCAs already included in membership applications submitted to the OPTN, types of VCA transplants that have been performed, and types of potential emerging VCA transplants reported in literature and media. The nomenclature used is intended to be broad enough to capture vascularized allografts that are anatomically linked and those that may fall under the umbrella of a surgical specialty, as HRSA clarified that the intent of the regulatory language was not to require granular detail for each specific body part. Therefore, using nomenclature of, and similar to, "Upper Limb" is acceptable.

In December 2015, the Committee discussed the types of VCAs as well as specific examples that would fall under each type. The Committee unanimously approved the following:

- 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, scalp, larynx, trachea, thyroid, or parathyroid gland)
- Abdominal wall (including, but not limited to, symphysis pubis and other vascularized pelvic elements)
- Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder)
- 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)
- Adrenal gland
- Spleen
- Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap)

How well does this proposal address the problem statement?

Current VCA Transplantation in the U.S.

The primary therapeutic goal of any VCA transplant is functional restoration. There may be cosmetic improvements resulting from a VCA transplant, but the primary goal is restoring native function. Beginning in July 2014, transplant hospitals began to submit applications to the OPTN to perform VCA transplants (**Table 1**).

Table 1. Approved VCA Transplant Programs as of December 25, 2015.

VCA Program Type	N
Upper Limb	17
Head and Neck	14
Abdominal Wall	13
Genitourinary	8
- Uterine	3
- Penile	2
- Genitourinary, not specified	3
Lower Limb	1
Total	53

As of December 25, 2015, there were 53 VCA programs located at 24 transplant hospitals. There were 17 approved upper limb, 14 head and neck, and 13 abdominal wall transplant programs. Upper limb, head and neck, and abdominal wall transplant programs represent the current clinical practice in the U.S.; as of December 25, 2015, no genitourinary or lower limb VCA transplants have been performed in the U.S. The applications for VCA program types received by the OPTN were considered when creating the list of covered body parts. As a result, the VCA program types in the table above were included in the list of covered body parts.

Emerging VCA Transplants

There are four emerging areas of VCA transplantation in the U.S.: genitourinary organs; uterus; lower limb; and musculoskeletal composite grafts. Additionally, there are two areas of VCA transplantation where innovation may occur and those body parts are included on the list: adrenal gland and spleen.

Genitourinary Organs

Genitourinary organ transplantation represents one emerging area of VCA transplantation. Both male and female genitalia would be included under this title. These structures could be transplanted in instances of severe trauma or prior surgical complications where urological reconstruction was previously unsuccessful, or not possible.

Since July 3, 2014, eight transplant hospitals have applied for genitourinary/penile/urogenital transplant programs, but no transplants of these organs have occurred since then. The OPTN is not aware of any genitourinary, penile, or urogenital transplants occurring in the U.S. prior to July 3, 2014. However, genitourinary organ transplantation is documented in the media and peer-reviewed literature. The first case of successful male genitalia transplant occurred in South Africa in December 2014⁸. This transplant was performed on a male recipient who had surgical complications from circumcision. One earlier unsuccessful case occurred in China in 2006⁹. One recent article profiling a genitourinary transplant program in the U.S. reported more than 1,350 wounded service members have suffered genitourinary trauma in combat between 2001 to 2013¹⁰. In addition, individuals with injuries from occupational accidents may benefit from genitourinary transplantation.

Uterus Transplantation

Uterus transplantation represents a second emerging area of VCA transplantation. The OPTN has approved uterus transplant programs at three OPTN-member transplant hospitals as of December 25, 2015. However, no uterus transplants have occurred since VCAs became governed by the OPTN on July 3, 2014. The OPTN is not aware of any uterus transplants occurring in the U.S. prior to July 3, 2014.

This type of transplant could treat a narrow classification of fertility problems: uterine factor infertility (UFI). Estimates on the incidence of UFI in women of childbearing age have been reported between 3-5%¹¹.

⁸ Bateman, Chris. 2015. "World's First Successful Penis Transplant at Tygerberg Hospital." *South African Medical Journal* 251-252, http://www.scielo.org.za/scielo.php?pid=S0256-95742015000300009&script=sci_arttext&tlang=pt

⁹ Zhang, Li-Chao. 2013. "Ethical Issues in Penile Transplantation." *Asian Journal of Andrology* 795-800, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3739079/pdf/ajaa201088a.pdf>

¹⁰ Grady, Denise. 2015. "Penis Transplants Being Planned to Help Wounded Troops." *New York Times*, December 6: A1. http://www.nytimes.com/2015/12/07/health/penis-transplants-being-planned-to-heal-troops-hidden-wounds.html?_r=0

¹¹ Tzakis, Andreas G. 2015. "The First Live Birth Subsequent to Uterus Transplantation." *Transplantation* 8-9, http://journals.lww.com/transplantjournal/Citation/2015/01150/The_First_Live_Birth_Subsequent_to_Uterus.5.aspx

Uterus transplants may also be an option when surrogacy or adoption is not possible due to ethical, religious, and other reasons. Although no uterus transplants have occurred in the U.S., uterus transplants have occurred in Sweden with three live births reported¹². Prior uterus transplants have occurred internationally in Saudi Arabia (2000) and Turkey (2011)¹³.

Uterus would be classified under the title of “genitourinary organs” under this proposal.

Lower Limb Transplantation

Lower limb transplantation is a third emerging area of VCA transplantation. Lower limb transplantation may be a therapeutic alternative in cases of limb loss due to trauma or underlying congenital disorders. There is one approved lower limb transplant program in the U.S.; however, no lower limb transplants have been performed since VCAs became governed by the OPTN on July 3, 2014. The OPTN is not aware of any lower limb transplants occurring in the U.S. prior to July 3, 2014. One case of lower limb transplant was reported in Spain in July 2011¹⁴.

Musculoskeletal Composite Graft Transplantation

Musculoskeletal composite graft segments are a fourth emerging area of VCA transplantation. Musculoskeletal grafts may include vascularized allografts for post-traumatic reconstruction or reconstruction for osteomyelitis. Vascularized joint transfers of the ankle, elbow, hip, knee, shoulder or wrist joint may be appropriate in young patients that are not candidates for conventional arthroplasty, or in cases of joint loss due to ballistic injury or infection. Other musculoskeletal composite graft components include functional muscle transfers for functional reconstruction, or coverage of major soft tissue defects. As of December 25, 2015, there are no approved VCA programs in the U.S. for musculoskeletal composite graft segments.

Adrenal Gland and Spleen Transplantation

The Committee agreed that adrenal gland and spleen transplants represent areas of innovation in VCA transplantation and may occur in the near future. While clinically accepted as “organs”, adrenal glands and spleens are not legally identified as covered human organs in NOTA or the Final Rule. The Committee discussed and agreed that these two body parts meet the definition of VCA in the Final Rule according to the nine criteria. Including adrenal gland and spleen transplants on a list of covered body parts would legally define them as VCAs and provide transparency that oversight would fall under the OPTN/UNOS. As of December 25, 2015, the OPTN has not received any applications for VCA programs seeking to transplant adrenal glands or spleens involving living or deceased donors.

The primary goal of this proposal is for OPTN/UNOS bylaws and policies to be consistent with the Final Rule. The list of covered body parts is not an endorsement of research on a new type of organ transplant by the Department of Health and Human Services or the OPTN. The intent of these modifications is for the OPTN bylaws and policies to be compliant to federal regulation, to provide transparency in what body parts are VCA organs, and to define the scope of oversight by the OPTN.

¹² Brannstrom, Mats. 2015. "The Swedish Uterus Transplantation Project: The Story Behind the Swedish Uterus Transplantation Project." *ACTA Obstetricia et Gynecologica* 675-679, <http://onlinelibrary.wiley.com/doi/10.1111/aogs.12661/full>

¹³ Arora, Kavita. (2013). "Uterus Transplantation: Ethical and Regulatory Challenges." *Journal of Medical Ethics*, 396-400.

¹⁴ Cavadas, P.C. 2013. "Bilateral Transfemoral Lower Extremity Transplantation." *American Journal of Transplantation* 1343-1349, <http://www.medscape.com/viewarticle/805143>

Which populations are impacted by this proposal?

The primary impact of this proposal will be on transplant hospitals with approved VCA programs. Between July 3, 2015 and December 25, 2015, there have been nine VCA transplants performed in the U.S. and nine candidates waiting for VCA transplants as of December 25, 2015 (**Table 2**).

Table 2. VCA Transplants Performed During 7/3/2014 – 12/25/2015 and Candidates Waiting for VCA Transplants as of 12/25/2015 by Type.

VCA Type	VCA Transplants, 7/3/2014-12/25/2015		VCA Candidates on the Waiting List as of 12/25/2015	
	N	%	N	%
Abdominal Wall	1	11.1	-	-
Head and Neck: Craniofacial	3	33.3	-	-
Head and Neck: Scalp	1	11.1	-	-
Upper Limb, Bilateral	2	22.2	6	66.7
Upper Limb, Unilateral	2	22.2	3	33.3
Total	9	100.0	9	100.0

Of the nine VCA transplants, one was an abdominal wall transplant, four were head and neck transplants (including three face and one scalp), two were bilateral upper limb transplants, and two were unilateral upper limb transplants. As of December 25, 2015, six candidates were waiting for bilateral upper limb transplants and three were waiting for unilateral upper limb transplants. To date, there have been no lower limb, uterus, genitourinary, penile, or urogenital candidates or transplants performed in the U.S.

This proposal will also impact any hospital seeking to transplant a body part on the list in OPTN/UNOS Bylaws and Policies. Hospitals must be OPTN members and apply for approval of a VCA transplant program prior to transplanting organs included on the list of covered body parts.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal
2. *Improve equity in access to transplants:* There is no impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal
5. *Promote the efficient management of the OPTN:* This project will address an inconsistency with between the OPTN Final Rule and OPTN Policies and Bylaws pertaining to VCAs.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The submission of applications and the successful designation and approval of VCA programs at member transplant hospitals will be the basis for evaluating this proposal. The following information will be monitored every 3 months following implementation of the policy for the duration that is to be determined.

- The number of approved VCA programs by type
- The number of candidates added to the VCA waiting list by center and VCA type
- The number of VCA transplants by center and VCA type
- The number of candidates still waiting for VCA by center and VCA type

How will the OPTN implement this proposal?

UNOS staff will amend the formal membership application to reflect the new list of VCA types. The MPSC will review these VCA applications in collaboration from the VCA Committee and may offer interim approval. Final approval for a VCA program will rest with the OPTN/UNOS Board of Directors.

Implementation of these new bylaw requirements would follow the creation and approval of the OMB form and be effective pending programming and notice to OPTN members.

UNOS systems that categorize VCA candidates and transplants by VCA type will need to be re-categorized. This will include re-categorizing existing data and changing systems so that members can use the new categories for new data. This will impact the following: the VCA Candidate Registration; Candidate Removal; Transplant Contact Information for Organ Offers; the Transplant Recipient Registration; and Transplant Recipient Follow-up worksheets.

How will members implement this proposal?

All approved VCA “other” transplant programs would need to reapply for OPTN/UNOS membership. Key personnel proposed to fill primary transplant physician or primary transplant surgeon roles would need to meet OPTN membership criteria in effect at the time of the program’s application.

Will this proposal require members to submit additional data?

A transplant program must submit an application to the OPTN to be approved for VCA. The application will be updated to reflect the new classifications. New information collection will be limited to the training and experience qualifications of the key personnel, as stated in this proposal. Consistent with the OPTN Principles of Data Collection, additional data collection will be limited to only that which is necessary to “determine if institutional members are complying with policy.”

How will members be evaluated for compliance with this proposal?

The MPSC will review VCA transplant program applications to determine compliance with these proposed Bylaws. Upon implementation, the OPTN Contractor will facilitate the key personnel change process and the MPSC will review key personnel change applications to ensure ongoing compliance with the Bylaws when changes to a transplant program’s primary surgeon or primary physician occur.

Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

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.2 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.~~

38 **Appendix M: Definitions**

39 **V**

40 **Vascularized Composite Allograft (VCA)**

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

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

55 The following body parts are considered VCAs:

- 56
- 57 □ Upper limb (including, but not limited to, any group of body parts from the upper limb, or radial
58 forearm flap)
- 59 □ Head and neck (including, but not limited to, face including underlying skeleton and muscle, scalp,
60 larynx, trachea, thyroid, or parathyroid gland)
- 61 □ Abdominal wall (including, but not limited to, symphysis pubis and other vascularized pelvic elements)
- 62 □ Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia,
63 or urinary bladder)
- 64 □ Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and
65 transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior
lateral thigh flaps, or toe transfers)
- 66 □ Adrenal gland
- 67 □ Spleen
- 68 □ Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or
any other vascularized muscle, bone, nerve, or skin flap)

75 **Policy 1: Administrative Rules and Definitions**

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77 **1.2 Definitions**

78 **V**

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- 87 5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the
88 organ relating to the organ's utility for reconstruction, repair, or replacement).
- 89 6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that
90 performs the same basic function or functions in the recipient as in the donor).
- 91 7. Not combined with another article such as a device.
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94 disease risk to the recipient.

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99 forearm flap)
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101 larynx, trachea, thyroid, or parathyroid gland)
- 102 • Abdominal wall (including, but not limited to, symphysis pubis and other vascularized pelvic elements)
- 103 • Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia,
104 or urinary bladder)
- 105 • Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and
106 transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior
107 lateral thigh flaps, or toe transfers)
- 108 • Adrenal gland
- 109 • Spleen
- 110 • Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or
111 any other vascularized muscle, bone, nerve, or skin flap)

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