DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington, DC 20420

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Reply to: **10NC2**

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UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

HAND AND FACE TRANSPLANTATION/VASCULARIZED COMPOSITE ALLOGRAFT TRANSPLANTATIONS

1. Purpose: This Veterans Health Administration (VHA) Information Letter provides information on hand and face transplantation and the role VHA has in providing care and treatment to wounded warriors, in either active duty or Veteran status, or eligible and enrolled Veterans who have experienced non-combat related injuries and desire consideration for such services.

2. Background:

a. Hand and face transplantations are characterized as Vascularized Composite Allograft (VCA) transplantations, defined as the implantation or transfer of composite tissue from one human to another.

b. Hand transplants represent the majority of VCA transplantations performed in the United States, and they number less than 50 since the first successful hand transplant in 1999. The overall short and long-term outcomes of these procedures are unknown.

c. On July 3, 2013, the Department of Health and Human Services (HHS) published a final rule in the Federal Register, 78 FR 40033, to add VCA to the definition of organs covered by the rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) under the National Organ Transplantation Act (NOTA) of 1984, as amended. In effect, this rulemaking establishes the following:

(1) Transfer of oversight authority of VCA transplantation from the Food and Drug Administration (FDA) to the Health Resources and Services Administration (HRSA);

(a) Mandatory VCA allocation policies;

(b) Direct coordination for procurement efforts;

(c) Consistent application of recovery and logistics processes; and

(d) Mandatory outcomes reporting.

d. As of June 1, 2013, the Department of Defense (DoD) Military Treatment Facilities (MTF) reported 1,602 amputee patients of which 502 sustained multiple amputations related to Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND). These numbers represent the numbers of individuals who sustained the loss of an arm, leg, hand, and/or foot; they do not include amputations of a digit (finger or toe).

e. DoD provides grant support to established centers for the performance of face and hand transplants. As of June 1, 2013, DoD centers for hand transplantation include Emory University, the University of Pittsburgh Medical Center, the University of Louisville, and the Johns Hopkins School of Medicine. DoD centers for face transplantation include the Brigham and Women's Hospital and the Cleveland Clinic. DoD supports ongoing research in hand transplantation under the Armed Forces Institute for Regenerative Medicine (AFIRM) and through service-specific research grants.

f. VCA, including hand transplantation, is not recognized by the Centers for Medicare and Medicaid Services (CMS) as medically necessary. The American Society for Reconstructive Transplantation has published reasons why VCA should be considered standard of care and medically necessary treatment, and those reasons are available for viewing at http://www.a-s-r-t.com/education/education.html.

3. Access of Active Duty Servicemembers and Veterans in the Care and Treatment of Hand and Face Transplantations; Application of VHA Policy on Eligibility, Care Management and Payment for Services:

a. At this time, VCA is not a generally accepted standard of medical practice determined by appropriate health care professionals to promote, preserve or restore the health of the individual. Consequently, hand and face transplantation are not included in the care and services provided by VHA under the Department of Veterans Affairs (VA) Medical Benefits Package (see Title 38 Code of Federal Regulations (CFR) 17.38).

b. VHA supports the DoD grant and research program in VCA in the following manner:

(1) The Atlanta VA Medical Center has established an Institutional Review Board-approved research protocol in pre- and post-operative care allowing eligible and enrolled Veterans with upper extremity amputations access to the Emory University DoD-supported hand transplantation program.

(2) By invitation, VHA provides subject matter expert representatives to the DoD Hand and Face Transplantation Advisory Board, which reviews candidate selection pre-transplantation.

c. VA will provide post-operative, follow-on care, and treatment under 38 United States Code (U.S.C.) 8111 to Active Duty Servicemember VCA recipients covered under DoD grant or research protocols with required DoD authorization, as stated in VHA Directive 2010-051,

Treatment of Active Duty and Reserve Component Servicemembers in VA Health Care Facilities, in the following instances:

(1) If the Active Duty Servicemember VCA recipient is located at a VCA center or DoD Military Treatment Facility (MTF), clinical orders from a MTF clinician specifying which services VA is authorized to provide, as well as verification of DoD authorization through the Military Medical Support Office (MMSO), or TRICARE Managed Care Support Contractor (MCSC), are required.

(2) If the Active Duty Servicemember VCA recipient presents to a VA medical facility for urgent or emergent care, the VA medical facility provides care and treatment first and notifies the MTF where the servicemember is enrolled, the MMSO Service Point of Contact (SPOC), or the regional TRICARE MCSC to seek authorization once the Active Duty Servicemember has been stabilized.

(3) If the Active Duty Servicemember VCA recipient presents to a VA medical facility for non-urgent or non-emergent care, the VA medical facility has to receive DoD authorization from the MTF, the MMSO SPOC, or the TRICARE MCSC prior to providing services. If the care required is not available at VA, the Non-VA Medical Care Program cannot be used.

d. VA provides coordinated care management to the Active Duty Servicemember VCA recipient authorized by DoD to receive inpatient or outpatient care and treatment at a VA medical facility as described in subparagraph 3.c.

(1) Designated MTFs have an assigned VA Liaison for Healthcare to ensure the transfer of Active Duty Servicemembers or Veterans from the MTF to a VA medical facility closest to the Servicemembers' or Veterans' homes for the most appropriate specialized services required by their medical condition (see VHA Handbook 1010.02, Department of Veterans Affairs Liaison for Healthcare Stationed at Military Treatment Facilities).

(2) A Federal Recovery Coordinator (FRC) reporting to the Office of the Secretary of VA is assigned to facilitate care coordination to any Active Duty Servicemember or Veteran, including any who have received a VCA secondary to catastrophic combat related injuries.

(3) Every VA medical facility has an OEF-OIF Program Manager whose responsibilities are to coordinate an OEF-OIF Care Management Team, including the activities of an OEF-OIF Case Manager to coordinate the care and services to an Active Duty Servicemember VCA recipient, and act as a point of contact to the VA Liaison for Healthcare and FRC, as applicable.

e. Any Veteran who receives a VCA, either through a DoD grant/research protocol or independently outside VA, may receive post-operative follow-on care and treatment at a VA medical facility if eligible for VA care (see VHA Handbook 1601A.02, Eligibility Determination).

f. An enrolled Veteran who receives a VCA, either through a DoD grant/research protocol or independently outside of VA, may receive pre-authorized post-operative follow-on care and

treatment at a non-VA medical center under the Non-VA Medical Care Program when referral is made by a VA physician (see VHA Directive 1601, Non-VA Medical Care Program).

(1) Payment for hospital care and outpatient care and qualifying non-emergent and emergent care, acquired with prior VA authorization, may be authorized if provided for under a contract or purchase order (individual authorization) under Title 38 U.S.C.1703, and 38 CFR 17.52 through 17.56 for those Veterans who are eligible under section 17.52.

(2) Subject to VA review, the expenses of emergency hospital or outpatient care provided without prior authorization from VA in a private or public (or Federal) hospital not operated by VA may be paid for or reimbursed by VA for certain Veterans with service-connected conditions in accordance with 38 U.S.C. 1728 and 38 CFR 17.120 through 17.132.

(3) It is VHA policy that admission of any Veteran to a private or public hospital at VA expense will be authorized only when VA health care facilities are not feasibly available, in accordance with 38 CFR 17.53.

(4) A VA medical facility may be considered as not feasibly available when the urgency of the applicant's medical condition, the relative distance of the travel involved, or the nature of the treatment required makes it necessary or economically advisable to use public or private facilities (see 38 CFR 17.53).

4. References:

a. VHA Directive 2010-051, Treatment of Active Duty and Reserve Component Servicemembers in VA Health Care Facilities

b. VHA Directive 2009-016, Notification of Admission or Discharge of Active Duty Personnel.

c. VHA Directive 1601, Non-VA Medical Care Program.

d. VHA Handbook 1010.01, Care Management of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) Veterans.

e. VHA Handbook 1010.02, Department of Veterans Affairs Liaison for Healthcare Stationed at Military Treatment Facilities.

f. Armed Forces Institute of Regenerative Medicine (AFIRM) Annual Report 2012 Technical Progress Reports (II-54) at http://www.afirm.mil/assets/documents/annual_report_2012.pdf.

g. The Department of Health and Human Services Final Rule, 78 FR 40033, dated July 3, 2013. See http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/html/2013-15731.htm

h. The American Society for Reconstructive Transplantation, Guidelines for Medical Necessity Determination for Partial or Full Transplantation of the Face, available at http://www.a-s-r-t.com/education/education.html

5. Inquiries. Questions regarding the clinical aspects of VCA Transplantation may be directed to the National Surgery Office (10NC2) at 202-461-7130. Questions regarding eligibility, enrollment, and reimbursement for services may be referred to the Chief Business Office (10NB) at 202-461-1589.

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