

INFORMATION PAPER

Military Vaccine Agency
25 Jun 2013

SUBJECT: Vaccinia Immune Globulin Intravenous (Human) (VIGIV)

1. Purpose. Define procedures for acquiring VIGIV

2. Facts.

a. The DoD requires smallpox vaccination of designated at-risk military personnel, DoD civilian personnel classified as emergency-essential per DoD Directive 1404.10, and members of CBRNE response teams (e.g., smallpox epidemic response teams, treatment teams, and public health teams). A small number of people may be at increased risk for side effects after receipt of, or exposure to, the smallpox vaccine. VIGIV is indicated for the treatment of certain adverse conditions induced by the smallpox vaccine.

b. The Deputy Director of the Military Vaccine (MILVAX) Agency will act as final releasing authority for DoD owned VIGIV.

c. Under routine circumstances, the need for VIGIV will be determined by the attending physician in collaboration with a Vaccine Healthcare Centers Network (VHCN) physician before administration. The VHCN will provide and coordinate professional consultation services to optimize both diagnosis of a potential vaccinia adverse event and clinical use of VIGIV.

3. Procedures

a. Clinician identifies an individual with adverse reaction who may benefit from treatment with VIGIV. This would include but is not limited to: aberrant infections induced by vaccinia virus that include accidental implantation in eyes, mouth, or other areas where vaccinia infection would constitute a special hazard; eczema vaccinatum; progressive vaccinia; severe generalized vaccinia; or vaccinia infections in people who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in people who have eczematous skin lesions because of either the activity or extensiveness of such lesions. VIGIV is not indicated for isolated vaccinia keratitis or post-vaccinial encephalitis.

b. Clinician will immediately begin the consultation process with the VHCN by calling the DoD Vaccine Clinical Call Center at 866-210-6469, available 24 hours a day, 7 days a week. The VHCN physician, or the MTF attending physician after collaboration with

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the VHCN physician, will notify the MILVAX Agency (LTC Jorge Carrillo, 703-681-5699) with case specifics (indication for VIGIV, number of vials required, receiving POC, etc.).

c. The Deputy Director of the MILVAX Agency or his designee will coordinate the shipment of all VIGIV to CONUS and OCONUS locations.

d. The attending clinician must review the VIGIV package insert and be familiar with the indications, contraindications, complications, as well as all factors that affect the safe administration of this product. The clinician then obtains needed specialty consults and administers VIGIV if expected benefit outweighs potential risks. The VHCN physician will coordinate any pre- and post-infusion labs with the attending clinician.

4. References.

a. Advisory Committee on Immunization Practices. Smallpox Vaccinations and Adverse Reactions, MMWR 2003;52(RR04): 1-28:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm>

b. Centers For Disease Control and Prevention. Surveillance Guidelines for Smallpox Vaccine (Vaccinia) Adverse Reactions, MMWR 2006;55(RR01);1-16

c. [Vaccinia](#) Immune Globulin Intravenous (Human), Cangene Corporation, Package Insert:

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm179513.htm>

d. Guideline for Obtaining Vaccinia Polymerase Chain Reaction (PCR) Assay Testing at: www.vhcinfo.org/documents/PCR_ALGORYTHM_2012b.pdf

e. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by Military Vaccine Agency: www.vaccines.mil/smallpox

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Approved by: LTC Carrillo