INFORMATION PAPER

DHA-IHD
26 Jul 2019

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, and members of Chemical Biological Radiological Nuclear and Explosives response teams response 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 smallpoxvaccine.

   b. VIGIV, manufactured by Cangene Corporation, is an FDA-licensed medical treatment for rare, but serious adverse events associated with smallpox vaccination. In 2011, representatives from Chemical Biological Medical Systems and the United States Army Medical Materiel Agency of the United States Army Medical Research and Materiel Command established a DoD VIGIV stockpile. Establishment of this stockpile allowed the DoD to pre-position stocks of VIGIV for more responsive worldwide administration of potentially life-saving treatments in response to emergencies. OCONUS stockpiles are maintained at Camp Foster, Okinawa Japan, U.S. Army Medical Materiel Center-Korea, and U.S. Army Medical Materiel Center-Europe, Pirmasens, Germany.

   c. Any Medical Director within the DHA-Immunization Healthcare Division (IHD) is delegated by the Director of the IHD to act as final releasing authority for DoD-owned VIGIV. The IHD will provide and coordinate professional consultation services to facilitate the diagnosis of a potential vaccinia adverse event requiring VIGIV and the clinical use of VIGIV.

   d. The DHA-IHD Medical Director overseeing the management of the patient requiring VIGIV will coordinate with USAMMA for the shipment of all VIGIV to CONUS and OCONUS locations.

3. Procedures.

   a. An experienced 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 inoculation 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. The attending physician will immediately begin the consultation process with the IHD by calling the DHA Immunization Healthcare Support Center at 877-438-8222 (DSN 312-761-4245), Option 1, available 24 hours a day, 7 days a week.

   c. Before Vaccinia Immune Globulin (VIGIV) is released, confirmation of vaccinia infection is required. This may be either through accepted clinical signs and symptoms, or through verification of infection (see IHD Vaccinia PCR Algorithm).

   d. To assist in the indication verification, dose determination, and shipping processes, the following information is required from the attending physician:

      (1) Age
      (2) Weight
      (3) Clinical Condition (i.e., stable, guarded, critical)
      (4) In-patient status (i.e., Doctor's office, ED, hospitalized, ICU)
      (5) Percent skin involvement
      (6) History of eczematous skin conditions
      (7) History of immunocompromising conditions
      (8) Blood Rh factor (to determine VIGIV lot to be used)
      (9) Dermatology and ID consultant availability
      (10) Clinical specimens availability
      (11) Digital photos representing various lesions and total surface involvement
      (12) Obtain list of other potential contacts
      (13) Date of his last smallpox vaccination (primary or re-vaccinee)
      (14) Number of vials required [wt(kg) x 6,000U/kg /50,000U/vial]
      (15) Mailing address (MTF 24 hr pharmacy) and receiving pharmacist's name and 24 hr contact number

e. The DHA-IHD physician will contact USAMMA Emergency Operations Center with the above information and begin the coordination process.

f. The attending physician 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 IHD physician will coordinate with the attending clinician to recommend any pre- and post-infusion labs, and management of any untoward VIGIV reactions.

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. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5501a1.htm

c. Vaccinia Immune Globulin Intravenous (Human), Cangene Corporation, Package Insert: http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM179514.pdf

d. Guideline for Obtaining Vaccinia Polymerase Chain Reaction (PCR) Assay Testing at: https://health.mil/Reference-Center/Fact-Sheets/2017/01/09/Guideline-for-Obtaining-Vaccinia-PCR-Assay

e. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by DHA-IHD: https://health.mil/smallpox

North Atlantic Region Vaccine Safety Hub
Approved: Deputy Chief, Immunization Healthcare Division
877-438-8222 (DSN 761-4245), option 1