

**University of Michigan Health System**  
**Department of Pharmacy Services**

**Procedures for Obtaining Varicella Immune Globulin (VZIG)**

As of October 27, 2004, Massachusetts Public Health Biologic Laboratories, the only U.S.-licensed manufacturer of varicella immune globulin (VZIG), discontinued all manufacturing of this product.

**In February 2006, an investigational (not yet FDA-approved) VZIG product, VariZIG™, became available under an investigational new drug application (IND) with an expanded access protocol.** VariZIG™ can be requested from the sole authorized U.S. distributor, FFF Enterprises (Temecula, California), for patients who have been exposed to varicella and who are at increased risk for severe disease and complications.

The FDA has not yet approved a program by which hospitals can acquire VariZIG™ inventory in advance. **Currently, the only mechanism by which VariZIG™ can be obtained is on a patient-by-patient basis after the appropriate release forms have been signed.**

An expanded access protocol under the IND application allows use of VariZIG™ for patients who meet criteria and who choose to participate. **The expanded access protocol received central IRB approval, and therefore, the FDA and UM IRBMED do not require local IRB approval prior to VariZIG™ being used.**

**To obtain VariZIG™:**

1. The requesting physician must obtain informed consent from the patient, by completing the:  
[Research Subject Information and Consent Form](#),  
[Research Subject Assent Form](#), and  
[Authorization to Use and Disclose Protected Health Information \(HIPAA Form\)](#)
2. The requesting physician must complete a [release form](#).
3. On the release form, the requesting physician should provide the following information:

**Pharmacy Information:**

Pharmacy Contact Name & Contact Details: Amy Skyles, Pharm.D., Investigational Drug Services  
Phone No.: (734) 936-7469  
E-mail Address: [ajskyles@med.umich.edu](mailto:ajskyles@med.umich.edu)  
Existing FFF Account: No (Invoice to be sent to Blood Bank)  
DEA Board of Pharmacy No.: AU7007467

**Shipping Address:**

**Blood Bank**  
University Hospital, Room 2F225  
University of Michigan Health System  
1500 East Medical Center Dr.  
Ann Arbor, MI 48109  
(734) 936-6888

4. The **completed release form** should then be **faxed** to FFF Enterprises at 1-800-418-4333.
5. The requesting physician must **contact FFF Enterprises** at 1-800-843-7477 (after business hours and on weekends, select the emergency order option) to inform them that a release form has been faxed.
6. The requesting physician must **contact Blood Bank** and alert them to the impending delivery of VariZIG™, and provide the name/contact information of the individual who should be contacted upon receipt of the VariZIG™ by the Blood Bank.
7. **VariZIG™ should be available within 24 hours** after receipt and approval of a release form by FFF Enterprises.
8. The patient will be charged for the cost of VariZIG™ (\$179.04/vial), and this is included in the informed consent. If third party coverage is not available, the patient or requesting physician's department will cover the cost.

The CDC's Advisory Committee on Immunization Practices (ACIP) currently recommends that VariZIG™ be considered in the following patient populations:

Immunocompromised patients

Neonates whose mothers have signs and symptoms of varicella around the time of delivery (i.e., 5 days before to 2 days after)

Premature infants born at  $\geq 28$  weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity

Premature infants born at  $< 28$  weeks of gestation or who weigh  $\leq 1,000$  g at birth and were exposed during the neonatal period, regardless of maternal history of varicella disease or vaccination

Pregnant women

Investigational VariZIG™ is expected to provide maximum benefit when administered as soon as possible after exposure, although it can be effective if administered as late as 96 hours after exposure; treatment after 96 hours is of uncertain value.

**Pleaser refer to the CDC website for more information regarding dosing and administration of VariZIG™ (also included in the release form):**

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55e224a1.htm>

Release forms are also available directly from the FFF Enterprises website:

<http://www.fffenterprises.com/Products/VariZIGINDProtocol.aspx> or by calling FFF Enterprises at 1-800-843-7477 (after business hours and on weekends, select the emergency order option).

Drug Information Service  
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