FDA Approval of an Extended Period for Administering VariZIG for Postexposure Prophylaxis of Varicella

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VariZIG (Cangene Corporation, Winnipeg, Canada) is the only varicella zoster immune globulin preparation available in the United States for postexposure prophylaxis of varicella in persons at high risk for severe disease who lack evidence of immunity to varicella and are ineligible for varicella vaccine. VariZIG is available in the United States through an investigational new drug (IND) application expanded access protocol (*1*). VariZIG is a purified immune globulin preparation made from human plasma containing high levels of anti–varicella zoster virus antibodies (immunoglobulin G). In May 2011, the Food and Drug Administration (FDA) approved an extended period for administering VariZIG. The period after exposure to varicella zoster virus during which a patient may receive VariZIG, which had been 96 hours (4 days), is now 10 days (*1*). VariZIG should be administered as soon as possible after exposure (*1*).

Limited data suggest that the incidence of varicella is comparable among persons who receive varicella zoster immune globulin within 4 days of exposure and those who receive it more than 4 days (up to 10 days) after exposure and attenuation of disease might be achieved with administration of varicella zoster immune globulin up to 10 days after exposure (*2*–*5*). One study indicated an increase in varicella incidence with increasing time between exposure and administration of the immune globulin, but disease was attenuated in all cases (*6*).

VariZIG can be obtained by health-care providers from the sole-authorized U.S. distributor, FFF Enterprises (Temecula, California), by calling 800-843-7477 at any time or by contacting the distributor online at http://www.fffenterprises.com. As with any product used under an IND protocol, patients must give informed consent before receiving the product.

Advisory Committee on Immunization Practices (ACIP) recommendations regarding indications for the use of VariZIG remain unchanged (*7*,*8*). Patients without evidence of immunity to varicella (i.e., without a health-care provider diagnosis or verification of a history of varicella or herpes zoster, documentation of vaccination, or laboratory evidence of immunity or confirmation of disease) who are at high risk for severe disease and complications, who have been exposed to varicella or herpes zoster, and are ineligible for varicella vaccine, are eligible to receive VariZIG (*7*). Patient groups recommended by ACIP to receive VariZIG include the following:

- 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 ≥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 ≤1,000 g at birth and were exposed during the neonatal period, regardless of their mothers' evidence of immunity status.
- Pregnant women.

VariZIG should be administered intramuscularly as directed by the manufacturer. Additional information on the process for obtaining VariZIG under the IND protocol, use of antiviral therapy if varicella occurs after

administration of VariZIG, and the interval between administration of VariZIG and varicella vaccine once the patient becomes eligible is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5508a5.htm (*8*).

References

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