



Clinical Advisory
FDA Approval of an Extended Period for Administering VariZIG
for Postexposure Prophylaxis of Varicella
April 24, 2012

VariZIG is the only varicella zoster immune globulin preparation available in the United States for postexposure prophylaxis of varicella in certain persons at high risk for severe disease who lack evidence of immunity to varicella and are ineligible for varicella vaccine. In Massachusetts, there has been a steep decline in the annual number of reported cases of varicella since the pre-vaccine era (varicella vaccine was licensed in 1995). However, MDPH still receives close to 1800 reports every year (including suspect, probable and confirmed cases) for an incidence rate of approximately 27 cases per 100,000 population annually.

VariZIG is available in the United States through an investigational new drug (IND) application expanded access protocol ([Morbidity and Mortality Weekly Report](#), March 30, 2012). VariZIG is a purified immune globulin preparation made from human plasma containing high levels of anti-varicella zoster virus antibodies. 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.** VariZIG should still be administered as soon as possible after exposure.

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. 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.

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.

The Advisory Committee on Immunization Practices (ACIP) recommendations regarding indications for the use of VariZIG remain unchanged. 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. 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 $\leq 1,000$ 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>.

Recommended Immunizations For Health-Care Personnel (HCP)	
Vaccine	Recommendations in Brief
Varicella	<p>2 doses of varicella vaccine, or serologic proof of immunity, or history of varicella disease</p> <p>All HCP should be immune to varicella. Documentation of immunity includes documentation of 2 doses, \geq 4 weeks apart; laboratory evidence of immunity; laboratory confirmation of disease; HCP diagnosis or verification of varicella or herpes zoster; or verification of history of varicella disease or of herpes zoster by a HCP (including school or occupational health nurse). Year of birth is not acceptable documentation of immunity for HCP for varicella. For more information on varicella and immunization of health-care personnel, see Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (CDC, MMWR 2011; 60(7), p. 21-25).</p>

Recommended Immunizations For Teachers and Day Care Staff	
Vaccine	Recommendations in Brief
Varicella	<p>2 doses</p> <p>Those born in the U.S. before 1980 are considered immune. For all others (those born in the U.S. in 1980 or after 1980, and those born outside the U.S. regardless of year of birth), varicella vaccine is recommended for those who do not have documentation of two doses of varicella-containing vaccine, a reliable history of varicella disease (physician diagnosis or personal recall) or serologic evidence of immunity.</p>

Vaccination of Students

Kindergarten Through 12th Grade

Beginning September 1, 2011, 2 doses of live varicella vaccine were required for students attending kindergarten and 7th grade (these doses must be given at least four weeks apart beginning at or after 12 months of age). Beginning on September 1, 2017, this requirement will apply to all students attending grades K through 12.

College

Beginning on September 1, 2011, 2 doses of live varicella vaccine were required for full-time freshmen, and all full- and part-time undergraduate and graduate students in a health science program who may be in contact with patients (these 2 doses must be given at least four weeks apart beginning at or after 12 months of age). Beginning on September 1, 2015, this requirement will apply to all postsecondary students.

References

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2. Evans EB, Pollock TM, Cradock-Watson JE, Ridehalgh MK. Human anti-chickenpox immunoglobulin in the prevention of chickenpox. *Lancet* 1980;315:354–6.
3. Miller E, Marshall R, Vurdien J. Epidemiology, outcome and control of varicella-zoster infection. *Rev Med Microbiol* 1993;4:222–30.
4. Enders G, Miller E. Varicella and herpes zoster in pregnancy and the newborn. In: Arvin A, Gershon A, eds. *Varicella-zoster virus: virology and clinical management*. Cambridge, UK: Cambridge University Press; 2000.
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6. Winsnes R. Efficacy of zoster immunoglobulin in prophylaxis of varicella in high-risk patients. *Acta Paediatr Scand* 1978;67:77–82.
7. [CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices \(ACIP\). MMWR 2007;56\(No. RR-4\).](#)
8. [CDC. A new product \(VariZIG\(tm\)\) for postexposure prophylaxis of varicella available under an investigational new drug application expanded access protocol. MMWR 2006;55:209–10.](#)