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

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. 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. 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 healthcare 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.ffenterprises.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:

- 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

Announcements: Living Well with Chronic Illness: a Call for Public Health Action

ON APRIL 30, 2012, THE INSTITUTE OF Medicine released the final version of a committee report titled, Living Well with Chronic Illness: a Call for Public Health Action. The independent report, funded by CDC and the Arthritis Foundation, identifies public health actions that might reduce disability and improve functioning and the quality of life of persons with chronic disease.

Beyond simply living longer, persons increasingly are interested in maintaining or even improving their capacity to live well over their entire lives. The committee defined the concept of living well as reflecting “the best achievable state of health that encompasses all dimensions of physical, mental, and social well-being.”
The committee settled on a single guiding principle for their deliberations and recommendations: to help each affected person, and the population as a whole, to live well, regardless of the chronic illness in question or a person’s current state of health. Instead of making recommendations for specific illnesses, the committee identified nine conditions that reflect the tremendous variation in chronic diseases and have had significant effects on the nation’s health and economy to use as examples. The committee concluded that the epidemic of chronic illness is moving toward crisis proportions but that maintaining or enhancing quality of life for persons living with chronic illnesses has not been given the attention it deserves.

The committee report offers 17 recommendations for immediate and specific steps CDC and other components of the U.S. Department of Health and Human Services, and other federal and state agencies, might take to address chronic illness. The report is available at http://iom.edu/reports/2012/living-well-with-chronic-illness.aspx.

Recommended Immunization Schedules for Persons Aged 0 Through 18 Years—United States, 2012

MMWR. 2012;61:1-4

Each year, the Advisory Committee on Immunization Practices (ACIP) publishes immunization schedules for persons aged 0 through 18 years. These schedules summarize recommendations for currently licensed vaccines for children aged 0 through 6 years and 7 through 18 years and include recommendations in effect as of December 23, 2011. Vaccination providers are being advised to use all three schedules (FIGURES 1-3) and their respective footnotes together and not separately.

A parent-friendly schedule for children and adolescents is available online at http://www.cdc.gov/vaccines/recs/schedules/chld-schedule.htm#printable.

Changes to the previous schedules include the following:

- Updates to Figure 1 (“Recommended immunization schedule for persons aged 0 through 6 years”):
  - Quadrivalent meningococcal conjugate vaccine (MCV4) purple bar has been extended to reflect licensure of MCV4-D (Menactra) use in children as young as age 9 months.
  - A wording change has been introduced in the hepatitis A (HepA) vaccine yellow bar; wording now states, “Dose 1.” A new yellow and purple bar has been added to reflect HepA vaccine recommendations for children aged 2 years and older.
  - Guidance is provided for administration of hepatitis B (HepB) vaccine in infants with birthweights ≤2,000 grams and ≥2,000 grams. Clarification is provided for doses after administration of the birth dose of HepB vaccine.
  - Rotavirus (RV) vaccine footnotes have been condensed.
  - Haemophilus influenzae type b (Hib) conjugate vaccine footnotes have been condensed, and use of Hiberix for the booster (final) dose has been clarified. Guidance for use of Hib vaccine in persons aged 5 years and older in the catch-up schedule has been updated.
  - Pneumococcal vaccine footnotes have been condensed.
  - Guidance is provided for use of measles, mumps, and rubella (MMR) vaccine in infants aged 6 through 11 months. Footnotes in the catch-up schedule have been updated.
  - HepA vaccine footnotes have been updated to clarify that the second dose of HepA vaccine should be administered 6-18 months after dose 1.
  - MCV4 footnotes have been updated to reflect recent recommendations published in MMWR.

- Influenza vaccine footnotes have been updated to provide guidance on live, attenuated influenza vaccine (LAIV) contraindications.
- Influenza vaccine footnotes also have been updated to clarify dosing for children aged 6 months through 8 years for the 2011-12 and 2012-13 seasons.
- Figure 2 (“Recommended immunization schedule for persons aged 7 through 18 years”) has been updated to include number of doses for each vaccine. Information regarding the recommended age (16 years) for the booster dose of MCV4 has been added.
- Tdap vaccine recommendations for children aged 7 through 10 years have been updated.
- Human papillomavirus (HPV) vaccine footnotes have been updated to include routine recommendations for vaccination of males.
- Varicella (VAR) vaccine footnotes have been condensed.
- Inactivated poliovirus vaccine (IPV) footnotes have been updated to include upper age limit for routine vaccination. IPV footnotes in the catch-up schedule have been condensed, and relevant wording added to Figure 3 (“Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind”).
- In the catch-up immunization schedule, HepA vaccine and HepB vaccine footnotes have been removed. Relevant wording has been added to Figure 3.
- MCV4 vaccine has been added to Figure 3 along with corresponding footnotes.

The recommended immunization schedules for persons aged 0 through 18 years and the catch-up immunization schedule for 2012 are approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians.