Update on Herpes Zoster Vaccine: Licensure for Persons Aged 50 Through 59 Years

Herpes zoster vaccine (Zostavax, Merck & Co., Inc.) was licensed and recommended in 2006 for prevention of herpes zoster among adults aged 60 years and older (*1*). In March 2011, the Food and Drug Administration (FDA) approved the use of Zostavax in adults aged 50 through 59 years (*2*). In June 2011, the Advisory Committee on Immunization Practices (ACIP) declined to recommend the vaccine for adults aged 50 through 59 years and reaffirmed its current recommendation that herpes zoster vaccine be routinely recommended for adults aged 60 years and older.

FDA approved the expanded indication for Zostavax in March 2011, based on a study of approximately 22,000 adults aged 50 through 59 years in the United States and four other countries. Half the study subjects received Zostavax, and half received a placebo. Study participants were then monitored for at least 1 year for the development of herpes zoster. Compared with placebo, Zostavax reduced the risk for developing herpes zoster by 69.8% (95% confidence interval = 54.1--80.6) (*3*).

At the February and June 2011 ACIP meetings, published and unpublished data were presented relating to the epidemiology of herpes zoster and its complications, and regarding herpes zoster vaccine safety, effectiveness, long-term protection, cost-effectiveness, and supply. Limited data are available on long-term protection afforded by herpes zoster vaccine administered to adults aged 60 years and older and those aged 50 through 59 years.

Merck is the only U.S. supplier of varicella zoster virus (VZV)-containing vaccines (Zostavax, varicella vaccine [Varivax], and combined measles, mumps, rubella and varicella vaccine [MMR-V, ProQuad]). Beginning in 2007, Merck has experienced production shortfalls of the bulk product used to manufacture VZV-based vaccines (*4,5*), leading to prioritized production of Varivax over Zostavax since 2008. As a result, filling of Zostavax orders has been delayed intermittently.

Considering all available evidence and the supply issues, ACIP declined to recommend the use of herpes zoster vaccine among adults aged 50 through 59 years and reaffirmed its existing recommendation that herpes zoster vaccine be routinely recommended for adults aged 60 years and older (*1*). ACIP will continue to monitor supply issues and might update recommendations regarding vaccination of adults aged 50 through 59 years when an adequate and stable supply of the vaccine is assured. Planned improvements by Merck in its production processes and the addition of new manufacturing facilities are expected to increase the supply of the vaccine during the next several years.

With the FDA approval, Zostavax is available in the United States for indicated use among adults aged 50 years and older. Contraindications to the use of Zostavax remain unchanged. Zostavax should not be given to pregnant women, persons with a primary or acquired immunodeficiency, or to persons with a history of anaphylactic reaction to gelatin, neomycin, or any other component of the vaccine. Herpes zoster vaccine can be administered simultaneously with other indicated vaccines (*1,6*).

For vaccination providers who choose to use Zostavax among certain patients aged 50 through 59 years despite the absence of an ACIP recommendation, factors that might be considered include particularly poor anticipated tolerance of herpes zoster or postherpetic neuralgia symptoms (e.g., attributable to preexisting chronic pain, severe depression, or other comorbid conditions; inability to

tolerate treatment medications because of hypersensitivity or interactions with other chronic medications; and occupational considerations). No data are available regarding the effectiveness of herpes zoster vaccine in adults who become immunosuppressed subsequent to vaccination. Questions regarding the supply of these Merck products should be addressed to Merck's Vaccine Customer Center by telephone (877-829-6372).

Reported by

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