

Herpes Zoster Vaccine (Zostavax[™])

The Immunization Practices Advisory Council (IPAC), a collaboration of the New Mexico Department of Health and the New Mexico Immunization Coalition, recommends that all medical practices routinely offer immunization with herpes zoster vaccine (HZV) to all persons ages ≥ 60 . Only a single dose is recommended. A major impediment to obtaining the ZostavaxTM vaccine is reimbursement issues. See "How to Obtain the Vaccine for Your Patient" on page 2.

Latent varicella-zoster virus (VZV) infection is the cause of herpes zoster (HZ or Shingles) producing cutaneous dermatomal papulovesicular lesions and sensory nerve pain; it may be associated with complications, including disseminated VZV infection, bacterial super infection, ophthalmic zoster, and post-herpetic neuralgia (PHN). PHN, the most frequent and severe complication of HZ occurs in 7-25% of persons contracting HZ, with increasing prevalence after age 60. Approximately 1 million cases of HZ occur annually and the lifetime risk of HZ is 50% for those age ≥80.

Herpes zoster vaccine (HZV), ZostavaxTM, is a live attenuated virus vaccine indicated for the prevention of herpes zoster in individuals age \geq 60. The vaccine is not indicated for the treatment of zoster or PHN; nor for the prevention of varicella infection. HZV provides a minimum dosage of 19,400 plaque forming units of VZV in a single standard dose (0.65 ml), which is more than 10x the dose of varicella virus in current vaccines (VarivaxTM) licensed in the U.S. for prevention of varicella (Chickenpox).

Who should receive Zoster vaccine

- All persons age 60 or older.
- A single lifetime dose is recommended; no additional booster doses are recommended. Doses may be given and are recommended at age 60 or older. Before routine vaccination, it is not necessary to ask about the history of varicella or serologically test for varicella. However, doses given in persons older than 69 are progressively less effective at preventing the occurrence of zoster disease or its complications (effectiveness, 64% at age 60-69; 41% at age 70-79 and 18% at age ≥80). Incidence and severity of PHN is reduced at all ages, but the sooner HZV is given after 60, the more effective it is.
- Second cases of zoster are rare and the effectiveness of HZV in persons who have previously experienced HZ infections is unknown. A single dose is recommended for all persons ≥60 including those with a previous history of zoster.
- HZV may be administered with other indicated inactivated vaccines, including influenza, TD, Tdap and conjugated and polysaccharide pneumococcal vaccines.

Side effects and adverse reactions

- Local reactions: Redness (36%), tenderness (33%), swelling (25%), itching (6.5%), warmth (1.5%) hematoma (1.4%).
- Zoster-like rashes have been observed in some patients; none were related to the vaccine virus.

Contraindications for Zoster Vaccine

- A history of previous anaphylactic reaction to any of the vaccine components (gelatin, neomycin) is a contraindication. Previous neomycin dermal reaction is not a contraindication.
- HZV should not be administered to individuals with a history of primary or acquired immunodeficiency, leukemia, lymphoma, any other malignant neoplasm affecting the bone marrow or lymphatic system, or HIV infection or AIDS. HZV is a live attenuated VZV vaccine and administration to persons with immunosuppression may result in disseminated disease.

- HZV should not be administered to persons receiving antiviral medications for herpes, varicella or zoster infections.
- HZV should not be administered to a woman who is pregnant or might be pregnant.

Precautions for Zoster Vaccine

- Transmission of HZV virus may occur rarely between those vaccinated and susceptible contacts, but HZV is not contraindicated in households with immunosuppressed persons.
- HZV is not recommended or indicated for prevention of primary varicella disease.
- The duration of protection beyond 4 years is unknown. Revaccination has not been evaluated nor is it currently recommended. Although HZV is licensed for persons age ≥50, the ACIP recommends that routine HZV be given only once at age ≥60.

How to store and administer the vaccine

- HZV should be stored frozen in a temperature-monitored freezer (-15°C., +5°F., or colder) and should be reconstituted immediately upon removal from the freezer; the diluent should be stored separately at room temperature.
- HZV should be administered immediately after reconstitution; the reconstituted solution is semi-hazy to translucent, off-white to pale yellow. Do not freeze reconstituted vaccine; it should be discarded if not used within 30 minutes.
- Use separate sterile needles for reconstitution and administration of Zostavax. The dose is 0.65 ml administered subcutaneously in the upper deltoid region.

How to obtain the vaccine for your patient

Whenever possible HZV should be given when the patient has insurance coverage between 60-65 years of age, prior to enrolling in Medicare. Vaccine procurement and financing may be difficult for HZV, particularly after persons are enrolled in Medicare. This is the primary cause for a much lower uptake than might be expected owing to the severity of the disease prevented. The following recommendations are provided to minimize difficulties in vaccine procurement and in order of the most preferred strategy:

Immunization prior to 65 years of age

- Patients with insurance: Whenever possible, immunize patients between ages 60-64. In this age group, most private health insurance payers cover the vaccine. It can be given in an office that administers vaccines, and, in addition, the vaccine is most effective for this age group. Practices may need to receive prior approval from plans before administering vaccine and co-pays can be substantial (e.g., up to \$90).
- Manufacturer assistance programs. Uninsured low-income patients may be eligible for free vaccine through the Merck Patient Assistance Program. Go to www.merckhelps.com or call 1-800-727-5400 for information on eligibility and application.

Medicare: For patients ≥65, Medicare treats Zostavax as a prescription benefit and it is covered under part D for those seniors who have elected part D coverage. Many pharmacies offer and may administer Zostavax[™] in New Mexico and often have more experience in submitting claims under Medicare Part D. To find a pharmacy that will administer Zostavax[™] go to the Merck Adult Vaccination Locator website to search by zip code or by state. The patient should call ahead to determine when they can obtain the vaccine. If a prescription is written, the pharmacist does not need to screen the patient for appropriateness for the immunization.

Medicare supplemental plans or private insurance: Some patients ≥65 who are on Medicare, but who are not enrolled in a Part D plan, may have coverage through their secondary insurance. Coverage for these individuals would be under a medical benefit, and billing would occur as for those under 65, by billing the secondary insurer directly for the vaccination, or by billing the secondary insurer via the Medicare Part B contractor.

Suggestions for third party reimbursement

Providers may use the vaccination administration charge 90471 or 90472 (if more than a single vaccine is being given). For those 60-64 years of age, a bill for the immunization itself can be sent to the insurance company specifying CPT code 90736. The same code may be used for billing Medicare Part D providers for the vaccine itself, as indicated above.

For further information

New Mexico Department of Health, <u>http://www.immunizenm.org</u> Centers for Disease Control and Prevention, <u>www.cdc.gov/vaccines/</u> Centers for Disease Control and Prevention Vaccination Information Statements, <u>http://www.cdc.gov/vaccines/hcp/vis/index.html</u> ACIP recommendations regarding HZV: <u>http://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf</u> CDC "Pink Book": <u>http://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html#patho</u>