

## **Outpatient Formulary Addition of Herpes Zoster Vaccine (Zostavax®)**

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**P&T Action:** In December, the Pharmacy and Therapeutics Committee approved the addition of the herpes zoster vaccine to the outpatient formulary. It was not added to the inpatient formulary. Effective January 1<sup>st</sup>, 2007, Zostavax® is available on the outpatient formulary at The Nebraska Medical Center.

### **Introduction**

Herpes zoster (shingles) is characterized by a unilateral, painful, rash with a dermatomal distribution, which usually resolves within 2-4 weeks. Other symptoms, such as headache, fever and fatigue, can occur. Anyone previously infected with chickenpox is at risk for developing shingles, with life-time risk of 24-30%. There are between 500,000 and 1 million cases occurring in the USA annually, with 40-50% of them occurring in people 60 years of age or older. Complications associated with herpes zoster include scarring, loss of sensation over the skin in the affected area, bacterial infections, and temporary or permanent nerve palsy. Eye lesions may result in ophthalmic complications and in some cases permanent blindness. The most common and significant complication associated with herpes zoster is post-herpetic neuralgia (PHN). This pain can be continuous or episodic and last months or even years.

### **Clinical Efficacy**

Zostavax® is indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older. A clinical trial following almost 40,000 patients for a median of 3.12 years showed that Zostavax® reduced overall incidence of herpes zoster by 51.3% and significantly reduced pain and discomfort associated with the disease. The burden of illness due to herpes zoster was decreased by 61.1% and the incidence of PHN by 66.5%.

### **Comparison with Other Treatments**

Zostavax® is the only available vaccine to prevent shingles in older adults. Current therapy for shingles involves antivirals such as acyclovir, valacyclovir and famciclovir. Treatment is usually most effective if started within 72 hours of the onset of lesions and is continued for 7-10 days. The treatment reduces the number of days of active infection and hastens the healing process. Other medications used for symptomatic relief are NSAIDs, opiates, anticonvulsants, pregabalin, tricyclic antidepressants, ophthalmic antivirals, and topical anesthetics (capsaicin, lidocaine).

### **Safety**

In a large trial of Zostavax®, injection site reactions, such as erythema (33.7%), pain/tenderness (33.4%), and swelling (24.9%), and headaches (1.4%) were the most common side effects of the vaccine. Zostavax® should not be administered to individuals with a history of anaphylactic reaction to gelatin, neomycin, or any other component of the vaccine, or patients who are pregnant or may be pregnant. Patients with a history of immunodeficiency, including those with leukemias, lymphomas, AIDS, or taking high-dose corticosteroids, or those with an active tuberculosis infection, should not receive Zostavax®.

### **Use**

Zostavax® is approved for use as a single subcutaneous injection in immunocompetent individuals 60 years of age or older. CDC ACIP recommends use of Zostavax® in all people age 60 and older, including those who have had a previous episode of shingles.

**Storage & Reconstitution**

Zostavax® should be stored frozen at an average temperature of -15°C (+5°F) or colder until it is reconstituted for injection. Before reconstitution, protect from light. Zostavax® should be reconstituted immediately upon removal from the freezer, using only the diluent supplied. The vaccine should be administered immediately after reconstitution to minimize loss of potency and should be discarded if not used within 30 minutes.

**Reimbursement**

Starting January 2007 Zostavax® will be covered by Medicare Part D as a prescription drug, with varying co-pays determined by the patient's specific drug plan. Medicare will not reimburse doctor offices for actual administration of Zostavax®.