Cigna Medical Coverage Policy

Subject: Zoster Vaccine Live (Zostavax®)

Effective Date: 12/15/2012
Next Review Date: 12/15/2013
Coverage Policy Number: 6020

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Hyperlink to Related Coverage Policies:
- Routine Immunizations

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna companies including plans formerly administered by Great-West Healthcare, which is now a part of Cigna. Coverage Policies are intended to provide guidance in interpreting certain standard Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supercedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2012 Cigna

Coverage Policy

Note: Immunizations are covered under most CIGNA medical plans which include a Preventive Benefit. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage. Many benefit plans specifically exclude immunizations that are for the purpose of travel or to protect against occupational hazards and risks.

If coverage is available under the benefit plan, the following conditions of coverage apply:

Cigna covers zoster vaccine live (Zostavax®) as medically necessary for individuals 60 years of age and older for the prevention of herpes zoster (shingles) including those who have had a previous episode of shingles as recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).

General Background

U.S. Food and Drug Administration (FDA) Approved Indications
Zostavax is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older. Zostavax is not indicated for the treatment of zoster or post-herpetic neuralgia (PHN). Zostavax is not indicated for prevention of primary varicella infection (Chickenpox).

FDA Recommended Dosing
Zostavax should be administered as a single 0.65 mL dose subcutaneously in the deltoid region of the upper arm. Do not inject intravascularly or intramuscularly.

**Drug Availability**
Zostavax is supplied in a package of 1 single-dose vial of lyophilized vaccine and a separate package of 10 vials of diluent or a package of 10 single-dose vials of lyophilized vaccine and a separate package of 10 vials of diluent.

**Disease Overview**
Shingles occurs when the varicella-zoster virus that causes chickenpox reactivates after lying dormant in the body, typically after several decades. Therefore, shingles can affect anyone who has had chickenpox. About half of all cases occur among men and women 60 years old or older. It is estimated that up to one million people in the United States suffer from shingles each year, and the incidence is expected to increase as the population ages. Shingles can also lead to complications, including post-herpetic neuralgia (PHN). Approximately 50% of shingles patients 60 years of age and older may develop PHN.

**Pharmacology**
Zoster vaccine live (Zostavax) is a lyophilized strain of live, attenuated varicella-zoster virus (VZV).

**Guidelines**
The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) (2011) recommend zoster vaccine for all persons aged >60 years who have no contraindications, including persons who report a previous episode of zoster or who have chronic medical conditions. The vaccine should be offered at the patient's first clinical encounter with his or her health-care provider. It is administered as a single dose subcutaneously in the deltoid region of the arm. A booster dose is not licensed for the vaccine. Zoster vaccination is not indicated to treat acute zoster, to prevent persons with acute zoster from developing PHN, or to treat ongoing PHN. Before administration of zoster vaccine, patients do not need to be asked about their history of varicella (chickenpox) or to have serologic testing conducted to determine varicella immunity.

In March 2011, the FDA approved the use of Zostavax in individuals 50 to 59 years of age for prevention of herpes zoster (shingles); however, the ACIP has not issued an affirmative recommendation for expansion of vaccination to this age group.

**Clinical Efficacy**
Efficacy of Zostavax was evaluated in the Shingles Prevention Study (SPS), a placebo-controlled, double-blind clinical trial in which 38,546 subjects 60 years of age or older were randomized to receive a single dose of either Zostavax or placebo. Subjects were followed for the development of zoster for a median of 3.1 years. The study excluded people who were immunocompromised or using corticosteroids on a regular basis, anyone with a previous history of Herpes Zoster (HZ), and those with conditions that might interfere with study evaluations, including people with cognitive impairment, severe hearing loss, those who were nonambulatory and those whose survival was not considered to be at least five years. Randomization was stratified by age, 60–69 and 70 years of age. The primary efficacy analysis included all subjects randomized in the study who were followed for at least 30 days post-vaccination and did not develop a case of HZ within the first 30 days post-vaccination. Zostavax significantly reduced the risk of developing zoster when compared to placebo. Vaccine efficacy for the prevention of HZ was highest for those subjects 60–69 years of age and declined with increasing age.

Overall risk for post-herpetic neuralgia was significantly decreased by 39% for those who developed herpes zoster despite vaccination. However, the vaccine's efficacy against post-herpetic neuralgia achieved statistical significance relative to placebo only among person's ages 70–79 years (55%). The vaccine was substantially less effective in preventing post-herpetic neuralgia occurrence in individual's ages 60–69 years or 80 years and older, (5% and 26%, respectively). Vaccination also was linked to a small decrease in the overall duration of post-herpetic neuralgia (20 vs. 22 days).

Clinical data from a randomized, double blind study [Zostavax Efficacy and Safety Trial (ZEST)] of 22,439 subjects aged 50-59 to evaluate the safety, immunogenicity and efficacy of Zostavax as compared to placebo was the basis for FDA licensure for this age group. Compared with placebo, Zostavax reduced the risk of developing shingles by 69.8% (95% CI [54.1, 80.6%] in subjects 50 to 59 years of age.
**Warnings and Precautions**
Transmission of vaccine virus may occur between vaccines and susceptible contacts. Vaccination with Zostavax does not result in protection of all vaccine recipients. The duration of protection beyond four years after vaccination is unknown. The need for revaccination has not been defined. A reduced immune response to Zostavax has been observed with concurrent administration of pneumococcal 23-valent vaccine (PPSV23; Pneumovax® 23), therefore separate administration of these vaccines by four weeks should be considered.

**Adverse Reactions/Contraindications**
The most common side effects reported with the use of Zostavax were redness, pain and tenderness, swelling at the site of injection, itching and headache.

Zostavax is not indicated for prevention of primary varicella infection (Chickenpox) and should not be used in children and adolescents. Zostavax should not be used in women who are or may become pregnant or in women who are nursing. Pregnancy should be avoided for three months following vaccination.

Hypersensitivity reactions including anaphylaxis have occurred with this vaccine. Zostavax is contraindicated in persons with a history of anaphylactic/anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; those with a history of primary or acquired immunodeficiency states, including leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; patients with AIDS or other clinical manifestations of infection with human immunodeficiency viruses; and individuals on immunosuppressive therapy. Use of the live attenuated vaccine in immunosuppressed individuals may result in a more extensive vaccine-associated rash or disseminated disease. Deferral of administration should be considered in acute illness (e.g., presence of fever) or in patients with active untreated tuberculosis.

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**Coding/Billing Information**

*Note:* This list of codes may not be all-inclusive.

**Covered when medically necessary:**

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<th>CPT** Codes</th>
<th>Description</th>
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<th>ICD-9-CM Diagnosis Codes</th>
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<tr>
<td>V04.89</td>
<td>Need for prophylactic vaccination and inoculation against certain viral diseases; other viral diseases</td>
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**References**


2. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a5.htm?s_cid=mm6044a5_e%0d%0a


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### Policy History

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<td>11/15/2007</td>
<td>6020</td>
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