



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Zoster Vaccine Live (Zostavax®)

Effective Date.....12/15/2010
Next Review Date.....12/15/2011
Coverage Policy Number 6020

Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	3
References	3
Policy History.....	4

Hyperlink to Related Coverage Positions

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant'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 group 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. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

Note: Vaccines 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.

If coverage is available for vaccines, then:

CIGNA covers one dose of 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 or as currently recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).

FDA Approved Indications

Zostavax is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older. Zostavax is not indicated for the treatment of zoster or post-herpetic neuralgia (PHN).

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

Zoatavax 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.

General Background

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. Up to half of all people living to age 85 will develop shingles during their lifetime. It is estimated that up to 800,000 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 postherpetic neuralgia (PHN). Approximately 25–50% of shingles patients older than 50 years of age may develop PHN.

Pharmacology

Zoster vaccine live (Zostavax) is a lyophilized strain of live, attenuated varicella-zoster virus (VZV). Initially, the virus was obtained from a child with naturally-occurring varicella, then introduced into human embryonic lung cell cultures, adapted to and propagated in embryonic guinea pig cell cultures and finally propagated in human diploid cell cultures. Zostavax, the only zoster vaccine on the market, was studied in approximately 38,000 individuals throughout the United States who were age 60 and older. Zostavax is indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older. Zostavax is not indicated for the treatment of zoster or postherpetic neuralgia or as a substitute for live varicella virus vaccine. It is not indicated for use in children.

Guidelines

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) (2009) 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.

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 postherpetic neuralgia was significantly decreased by 39% for those who developed herpes zoster despite vaccination. However, the vaccine's efficacy against postherpetic neuralgia achieved statistical significance relative to placebo only among person's ages 70–79 years (55%). The vaccine was substantially less effective in preventing postherpetic 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 postherpetic neuralgia (20 vs. 22 days).

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. The percent of significant adverse events observed in the study was not different between persons who received the vaccine versus placebo. In particular, injection-site adverse reactions occurred with increased frequency in the vaccine vs. placebo group (48% vs. 17%).

Zostavax should not be used in persons receiving immunosuppressive therapy, including high-dose corticosteroids, and in women who are or may become pregnant. According to the FDA, the safety and efficacy of Zostavax has not been evaluated in persons receiving immunosuppressive therapy or daily treatment with topical/inhaled corticosteroids/low-dose oral steroids. Use of the live attenuated vaccine in immunosuppressed individuals may result in a more extensive vaccine-associated rash or disseminated disease.

In addition, this vaccine 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 those with active untreated tuberculosis.

Coding/Billing Information

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

Covered when medically necessary:

CPT [®] Codes	Description
90736	Zoster (shingles) vaccine, live for subcutaneous injection

ICD-9-CM Diagnosis Codes	Description
V04.89	Need for prophylactic vaccination and inoculation against certain viral diseases; other viral diseases

References

1. Centers for Disease Control and Prevention (CDC). Press Release: CDC's Advisory Committee Recommends "Shingles" Vaccination. Available at: <http://www.cdc.gov/od/oc/Media/pressrel/r061026.htm>. Accessed on October 28, 2009.
2. Centers for Disease Control and Prevention (CDC). Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP), June 6, 2008. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5705a1.htm?s_cid=rr5705a1_e. Accessed on October 28, 2009.
3. FDA Licenses New Vaccine to Reduce Older Americans' Risk of Shingles. Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01378.html>. Accessed on October 30, 2006.
4. McEvoy GK, ed. AHFS 2009 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2009.
5. Merck and Co., Inc. Zostavax[®] (Zoster vaccine live) prescribing information. Whitehouse Station, NJ: Merck and Co., Inc. July 2009.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare Great-West Healthcare	11/15/2007	6020	Zoster Vaccine Live (Zostavax [®])

“CIGNA” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided exclusively by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Behavioral Health, Inc., Intracorp, and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. and Great-West Healthcare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company.

Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.