



# CIGNA MEDICAL 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 Bivalent Human Papillomavirus (Types 16 and 18) Recombinant Vaccine - Cervarix®**

Effective Date ..... 12/15/2010  
Next Review Date ..... 12/15/2011  
Coverage Policy Number ..... 9016

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## Hyperlink to Related Coverage Policies

### 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 bivalent human papillomavirus (HPV) recombinant vaccine (Cervarix®) as medically necessary for females age 10 to 25 for the prevention of infection from HPV serotypes 16 and 18 or as currently recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).

## FDA Approved Indications

Cervarix is indicated for the prevention of the following diseases caused by oncogenic human papillomavirus (HPV) types 16 and 18:

- cervical cancer
- cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma in situ, and
- cervical intraepithelial neoplasia (CIN) grade 1

Cervarix is approved for use in females 10 through 25 years of age.

## FDA Recommended Dosing

Immunization with Cervarix consists of 3 doses of 0.5-mL each, by intramuscular injection according to the following schedule: 0, 1, and 6 months. The preferred site of administration is the deltoid region of the upper arm.

## Drug Availability

Cervarix is available in 0.5-mL single-dose vials and prefilled TIP-LOK syringes.

## General Background

### Disease Overview

Genital HPV infections are the most common sexually-transmitted diseases in the United States, and HPV types 16 and 18 are the cause of about 70 percent of cervical cancers worldwide. There will be an estimated 11,270 new cases and 4,070 deaths from cervical cancer in the United States during 2009, according to the National Cancer Institute at the National Institutes of Health.

### Pharmacology

Cervarix is a non-infectious recombinant, AS04-adjuvanted vaccine that contains recombinant L1 protein, the major antigenic protein of the capsid, of oncogenic HPV types 16 and 18. The L1 proteins are produced in separate bioreactors using the recombinant Baculovirus expression vector system in a serum-free culture media composed of chemically-defined lipids, vitamins, amino acids, and mineral salts. Following replication of the L1 encoding recombinant Baculovirus in *Trichoplusia ni* insect cells, the L1 protein accumulates in the cytoplasm of the cells. The L1 proteins are released by cell disruption and purified by a series of chromatographic and filtration methods. Assembly of the L1 proteins into virus-like particles (VLPs) occurs at the end of the purification process. The purified, non-infectious VLPs are then adsorbed on to aluminum (as hydroxide salt). The adjuvant system, AS04, is composed of 3-*O*-desacyl-4'-monophosphoryl lipid A (MPL) adsorbed on to aluminum (as hydroxide salt). Cervarix is prepared by combining the adsorbed VLPs of each HPV type together with the AS04 adjuvant system in sodium chloride, sodium dihydrogen phosphate dihydrate, and water for injection.

### Clinical Efficacy

The primary clinical study for Cervarix included more than 18,000 women ages 15 years through 25 years in the United States and 11 other countries. Of these women, about 9,000 received Cervarix and 9,000 received Havrix, a licensed hepatitis A virus vaccine, as a control. The results showed that among women who had not already been infected by HPV types 16 and/or 18 before the start of the study, Cervarix was about 93 percent effective in preventing precancerous cervical lesions caused by these HPV types. Among all Cervarix vaccinees, which included those who tested negative for HPV 16 and/or 18, and those who tested positive at the start of the study, Cervarix was approximately 53 percent effective in preventing precancerous cervical lesions.

Studies also were performed to measure the immune response to Cervarix in girls ages 10 years through 14 years. Their immune response was similar to that of women ages 15 years through 25 years, indicating that the vaccine should have similar effectiveness in the 10 through 14 year age group. The current data show that Cervarix provides protection for about 6.4 years, but additional information on the length of protection is forthcoming.

### Ongoing Studies

Studies are underway to determine safety and efficacy of the use of Gardasil in women over the age of 26.

### Adverse Reactions

The safety of the vaccine was evaluated in about 24,000 girls and women, with about 13,000 of these receiving Cervarix. The most commonly reported adverse reactions in the Cervarix group included pain, redness, and swelling at the injection site, fatigue, headache, muscle and joint aches, and gastrointestinal distress.

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## Coding/Billing Information

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

**Covered when medically necessary:**

| <b>CPT® Codes</b> | <b>Description</b>  |
|-------------------|---|
| 90650             | Human Papilloma virus (HPV) vaccine, types 16, 18, bivalent, 3 dose schedule, for intramuscular use |

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

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**References**

1. GlaxoSmithKline. Cervarix® [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant]. Research Triangle Park, NC: GlaxoSmithKline. October 2009.
2. Advisory Committee on Immunization Practices (ACIP) – Vaccines for Children Program. Vaccines to Prevent Human Papillomavirus. Resolution No. 010/09-1. Available at: <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/1009hvp-508.pdf>. Accessed on November 10, 2009.

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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.