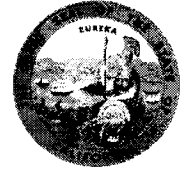




State of California—Health and Human Services Agency  
Department of Health Care Services



ARNOLD SCHWARZENEGGER  
Governor

DATE: October 18, 2007

MMCD Policy Letter 07015

TO:  Two-Plan Model Plans  
 Geographic Managed Care Plans (GMC)  
 County Organized Health Systems (COHS)

SUBJECT: Human Papillomavirus Vaccine

## BACKGROUND

Human papillomavirus (HPV) infection is the most common sexually transmitted infection in the United States. Approximately 20 million people are infected with HPV. Studies indicate that over 50 percent of sexually active women have been infected with genital HPV at some time during their lives

Although the majority of HPV infections cause no symptoms and are self-limited, persistent genital HPV infection can cause cervical cancer in women as well as other types of anogenital cancers and genital warts in both men and women. HPV 16 and HPV 18 make up 70 percent of all cervical cancers (Kahn, 2005) and 99 percent of all cervical cancers contain at least one high risk HPV type.

The U.S. Food and Drug Administration (FDA) advisory panel approved Gardasil on June 8, 2006. It is the first vaccine approved for prevention of cervical cancer. Gardasil is a recombinant vaccine that protects against four strains of HPV: 6, 11, 16, and 18. HPV strains 16 and 18 are associated with approximately 70 percent of all cervical cancer cases. HPV strains 6 and 11 are associated with about 90 percent of genital warts.

The FDA approved Gardasil for use in girls and women ages 9 to 26 years. Gardasil is approved for the prevention of cervical cancer, cervical precancers (cervical intraepithelial neoplasia (CIN) and adenocarcinoma in situ (AIS)), vulvar precancers (vulvar intraepithelial neoplasia (VIN)), and vaginal precancers (vaginal intraepithelial neoplasia (VaIN)) caused by HPV types 16 and 18. Gardasil is also approved for the prevention of genital warts and low-grade cervical abnormalities caused by HPV types 6 and 11.

Villa and associates (2005) evaluated the effectiveness of a prophylactic quadrivalent vaccine targeting the HPV types associated with 70 percent of cervical cancers (types 16 and 18) and with 90 percent of genital warts (types 6 and 11).

They concluded that a vaccine with HPV types 6, 11, 16, 18 could significantly reduce infection and clinical disease caused by these common HPV types.

Harper and colleagues (2004) agreed and reported that the bi-valent HPV16/HPV18 vaccine was effective in preventing incident and persistent cervical infections with HPV16 and HPV18, and associated cytological abnormalities and lesions (n = 1113).

The Advisory Committee on Immunization Practices (ACIP) recommends that routine pelvic exam and cytology screening for cervical cancer continue. Cervical cancer screening in the United States has decreased the morbidity and mortality from invasive cervical cancer by about 75 percent. It should be noted, the vaccine does not protect against HPV strains not included in the vaccine and it is not effective in individuals who are already infected with the four HPV strains in the vaccine.

## **POLICY**

1. Medi-Cal managed care considers Gardasil a medically necessary preventive service for girls and women 9 to 26 years of age.
2. Effective on and after October 13, 2006, Gardasil is a Medi-Cal managed care plan benefit for eligible girls and women from 9 up to and including 18 years of age, and the vaccine is covered through the Vaccine for Children (VFC) program.
3. Effective on and after January 1, 2007, Gardasil is a Medi-Cal managed care plan benefit for women 19 to 26 years of age.
4. Gardasil is recommended for routine immunization for females 11 to 26 years of age and for females 13 to 26 years of age who have not been vaccinated previously or have not completed the full vaccine series. It may be given as early as 9 years of age.
5. Gardasil:
  - Is administered in three separate 0.5mL intramuscular injections at 0, 2, and 6 months. It should be injected into the deltoid or anterolateral thigh.

- Ideally, the vaccine should be given before potential exposure to HPV through sexual contact. However, females who might have already been exposed to HPV also should be vaccinated.
- Sexually active females who have not been infected with any of the HPV vaccine types would receive full benefit from vaccination.
- Is not recommended for use during pregnancy. Any exposure during pregnancy should be reported to the vaccine pregnancy registry at 1-800-986-8999.
- Is considered investigational for all other indications.
- Is contraindicated in individuals who are hypersensitive to the active substances or to any of the components of the vaccine.

#### 6. Member Informing by Plans

- Members should be informed that Gardasil is a new benefit for women ages 9 to 26 that are not pregnant and may be effective for prevention of cervical cancer.

#### 7. Provider Training

Plans are responsible for ensuring training to network providers and their staff so that:

- Gardasil is provided using the current recommended Centers for Disease Control and Prevention (CDC) guidelines.
- Eligible providers should obtain the vaccine through the Vaccine for Children (VFC) program for eligible females 9 through 18 years of age.
- Health plan providers should inform the patient, parent, or guardian that HPV vaccination does not substitute for routine cervical cancer screening with routine pelvic examination and cytology screening.
- Providers document the immunization and provide HPV immunization data to the local immunization registry.

#### 8. Processes and Procedures

In accordance with contractual requirements to have processes and procedures to ensure that all medically necessary covered services are available and accessible Plans should:

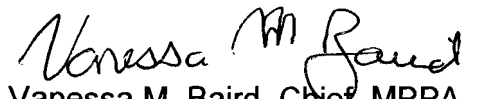
- Monitor the rate of HPV vaccine utilization.
- Promote HPV vaccination as per quality improvement strategies and provider training.

#### 9. Rate Adjustments

Capitation adjustments have already been included in the plan rates for 2007/08 and is noted in the Policy Change Number 21 in the May 2007, Medi-cal Estimate

Should you have any questions or require additional information regarding the content of this policy letter, please contact your contract manager.

Sincerely,

  
Vanessa M. Baird, Chief, MPPA  
Medi-Cal Managed Care Division

Attachment

**The above policy is based on the following references:**

1. Koutsky LA, Ault KA, Wheeler CM, et al. A controlled trial of a human papillomavirus type 16 vaccine. *N Engl J Med.* 2002; 347(21):1645-1651.
2. Harper DM, Franco EL, Wheeler C, et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: A randomized controlled trial. *Lancet.* 2004;364(9447):1757-1765.
3. Williamson AL, Passmore JA, Rybicki EP. Strategies for the prevention of cervical cancer by human papillomavirus vaccination. *Best Pract Res Clin Obstet Gynaecol.* 2005;19(4):531-544.
4. Kahn JA. Vaccination as a prevention strategy for human papillomavirus-related diseases. *J Adolesc Health.* 2005; 37(6 Suppl): S10-S16.
5. Villa LL, Costa RL, Petta CA, et al. Prophylactic quadrivalent human papillomavirus (types 6, 11, 16, and 18) L1 virus-like particle vaccine in young women: A randomized double-blind placebo-controlled multicentre phase II efficacy trial. *Lancet Oncol.* 2005;6(5):271-278.
6. Merck & Co., Inc. Gardasil (quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine). Prescribing Information. 9682300. White House Station, NJ: Merck; June 2006. Available at: <http://www.gardasil.com/>.
7. U.S. Food and Drug Administration (FDA). FDA licenses new vaccine for prevention of cervical cancer and other diseases in females caused by human papillomavirus. Rapid approval marks major advancement in public health. *FDA News.* P06-77. Rockville, MD: FDA; June 8, 2006. Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>.
8. Medical Letter. A Human Papillomavirus Vaccine 2006, 48:1241; pages 65-66.
9. [http://www.massgeneral.org/womenshealth/z\\_files/HPV\\_abnormal\\_PAP\\_final\\_112\\_20\\_06.doc](http://www.massgeneral.org/womenshealth/z_files/HPV_abnormal_PAP_final_112_20_06.doc)