

# UPMC Health Plan POLICY AND PROCEDURE MANUAL

**POLICY NUMBER: PAY.033**  
**REVISION DATE: 02/10**  
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**PAGE NUMBER: 1 of 5**

**SUBJECT:** Human Papilloma Virus (HPV) Vaccine  
**INDEX TITLE:** Medical Management  
**ORIGINAL DATE:** November 2006

**This policy applies to the following lines of business: (Check those that apply.)**

<b>COMMERCIAL:</b>					
HMO ( )		POS ( )		PPO ( )	
Fully Insured ( )		Self-funded/ASO ( )		HSA ( )	
Medicare Select ( )		Medicare Supplement ( )		Individual Product ( )	
<b>DPW-MA:</b>					
Health Choices ( )			Voluntary ( )		All (X )
<b>CMS-MA:</b>					
OH ( )		WV ( )		PA ( )	All (X )
HMO (X )		Specialty Needs Plan (X)		Part D ( )	PFFS (X )
PPO (X)					All ( )
<b>PID-CHIP/AdultBasic:</b>					
Free ( )		Sub ( )		Full ( )	
<b>ANCILLARY:</b>					
Dental ( )		Vision ( )			
<b>APPLICABLE TO:</b>					
Community Care ( )		Work Partners ( )			

## I. POLICY

It is the policy of UPMC Health Plan to recognize the value of preventive medicine as appropriate and consistent with good medical practice. UPMC Health Plan will provide coverage of vaccines for prevention of Human Papilloma Virus (HPV) infections and the likelihood of resulting diseases such as cervical and other gynecological cancers when the services are medically necessary or indicated as detailed in this policy and covered under the member's specific benefit plan.

## II. DEFINITIONS

N/A

## III. PURPOSE

The purpose of this policy is to define the appropriate indications for the HPV vaccine.

#### **IV. SCOPE**

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration and Claims departments.

#### **V. PROCEDURE**

##### **A. Medical Background**

Cervical cancer, a major health problem for women, is associated with several high-risk genotypes of human papillomavirus (HPV). In the United States, HPV is the most common sexually transmitted infection; and sexually active adolescents are at a particularly high risk for HPV infection. More than 99 % of cervical cancers contain at least one high-risk HPV type, and approximately 70 % of cervical cancers contain HPV16 or HPV18. These were the two most commonly detected HPV types in patients with invasive cervical adenocarcinoma and control subjects-found to be present in 82 % of the patients.

Gardasil is the first vaccine developed to prevent cervical cancer. Gardasil, a quadrivalent HPV (types 6, 11, 16, 18) recombinant vaccine, protects against the two strains of the HPV that are thought to cause about 70 % of all cervical cancer cases. The vaccine also protects against two other HPV (Types 6 & 11) strains that cause roughly 90 % of all genital warts.

However, the FDA panel notes that vaccination should not reduce the importance of routine screening for cervical cancer, which has been attributed to reducing cervical cancer rates nationwide by 75 %, and that the vaccine would not protect against the many other HPV strains not included in the vaccine or be effective in individuals who are already infected with the four HPV strains found in the vaccine.

Researchers know that the vaccine remains effective up to four years, but additional research is being done to see if a booster may be needed to continue its effectiveness in prevention of HPV types 6, 11, 16, and 18.

Cervarix is a recently FDA approved bivalent HPV vaccine for HPV types 16 & 18 for prevention against cervical cancer, cervical intraepithelial neoplasia (CIN) grade 2 or worse, adenocarcinoma in situ, and CIN grade 1.

##### **B. Indications**

The Quadrivalent HPV Vaccine (Gardasil) is indicated:

1. For girls and women who are between the age of 9 and 26 for prevention of the following disease caused by HPV types 6, 11, 16, and 18

- Cervical adenocarcinoma in situ (AIS)
  - Cervical intraepithelial neoplasia (CIN) grade 2 and 3
  - Vulvar intraepithelial neoplasia (VIN) grade 2 and 3
  - Vaginal intraepithelial neoplasia (VaIN) grade 2 and 3
  - Cervical intraepithelial neoplasia (CIN) grade 1
2. It is recommended that it be routinely given to girls 11-12 years old as a preventive service against cervical cancer.
    - The vaccine is administered in three separate intramuscular injections over a six-month period.
    - It is recommended that the second dose be administered two months after the first dose and the third dose six months after the first dose.
  3. For boys and men who are between the age of 9 and 26 for the prevention of genital warts caused by HPV types 6 and 11.

### **C. Limitations**

1. Gardasil is contraindicated in individuals who are hypersensitive to the active substances or to any of the excipients of the vaccine.
2. It is not recommended to be given during pregnancy.
3. If pregnancy is detected after vaccination has been given, the subsequent dosing should be delayed until the pregnancy has been completed.
4. The vaccine does not replace routine cervical cancer screening as per national guidelines for screening.
5. **The Bivalent HPV vaccine (Cervarix) is not covered**

### **D. Variations**

N/A

### **F. Quality Audit**

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan's Technology Assessment Committee or the Benefits Reimbursement Committee.

### **G. Records Retention**

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

## **H. References**

1. FDA News: P06-77, June 8, 2006.
2. Kaiser Network.org; Public Health & Education | Majority of Doctors Intend To Recommend HPV Vaccine for Children; Concern Over Parents' Role Remains, Surveys Say [Nov 30, 2005]  
<http://www.cdc.gov/std/HPV/STDFact-HPV.htm>
3. Sexually Transmitted Diseases Treatment Guidelines, 2006. MMWR 2006; 55 [No. RR-11].
4. Cates W, Jr. Estimates of the incidence and prevalence of sexually transmitted diseases in the United States. American Social Health Association Panel. Sex Transm Dis. 1999; 26(4): Suppl):S2-7.
5. Koutsky LA. Epidemiology of genital human papillomavirus infection. *Am J Med.* 1997; 102(5A):3-8.
6. U.S. Cancer Statistics Working Group. for Disease Control and Prevention and National Cancer Institute; 2005. Accessed December 6, 2005.
7. National Institutes of Health (NIH). *NIH Consensus Statement: Cervical Cancer.* 1996; 14:1-38.
8. Singh GK, Miller BA, Hankey BF, Edwards BK. Persistent area socioeconomic disparities in U.S. incidence of cervical cancer, mortality, stage, and survival, 1975-2000. *Cancer*, 2004; 101(5):1051-7.
9. Merck FDA approved label information -\_Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP)

**Disclaimer:**

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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