

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: PAY.033
REVISION DATE: 11/09
ANNUAL APPROVAL DATE: 01/10
PAGE NUMBER: 1 of 4

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

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

Commercial:				
HMO ()	POS ()	PPO ()	OOA ()	
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)	
Medicare Select ()	Medicare Supplement ()			
DPW-MA:				
Health Choices ()	Voluntary ()		All (X)	
CMS-MA:				
OH ()	WV ()	PA ()	All (X)	Other ()
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X)
PID-CHIP:				
Free ()	Sub ()	Full ()	All (X)	
APPLICABLE TO:				
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 cervical and other 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 quadri-valent HPV type 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 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.

Regular cytology screening may still be necessary after vaccination since it is possible that reduction in the prevalence of the currently most common HPV types (16 and 18) may result in a rise in the incidence of infections with other cancer-associated types.

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.

B. Indications

1. The HPV Vaccine (Gardasil) is indicated for girls and women who are between the age of 9 and 26.
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 in the upper arm 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.

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.

D. Variations

N/A

E. 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)

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