

## Evidence Based Guideline

# Human Papillomavirus (HPV) Vaccine

**File Name:** human\_papillomavirus\_(hpv)\_vaccine  
**Guideline Number:** EBG.MED1209  
**Origination:** 8/2006  
**Last Review:** 11/2006  
**Next Review:** 11/2008

### Description of Procedure or Service

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Cervical cancer is the second most common cancer in women attributing to approximately 3,700 deaths in the US each year. Researchers have been trying to identify the cause of cervical cancer for 2 decades. Studies found a link between human papillomavirus (HPV) viral infections and cervical cancer. Most infections caused by HPV clear up on their own and do not cause cancer. However, the majority of cervical cancer results from HPV infection. HPV is the most common sexually transmitted infection in the United States and it is estimated that 70 -80% of sexually active persons will be infected with genital HPV at some point in their life. Currently there are more than 20 million men and women infected with HPV with approximately 6 million new cases every year.

There are more than 100 types of the human papillomavirus (HPV). Some have no risk of cancer or genital warts. A few types can cause genital warts and approximately 15 high risk types can increase the risk of triggering cervical cancer.

The FDA has recently approved a cervical cancer vaccine, Gardasil, manufactured by Merck & Co., Inc. as a vaccine to prevent cervical cancer, precancerous lesions, and genital warts caused by HPV types 6, 11, 16, and 18. HPV types 16 and 18 cause approximately 70% of cervical cancers and HPV types 6 and 11 cause about 90% of genital warts. Gardasil is a recombinant vaccine (this means it contains no live virus) which is given in 3 doses over a 6 month period. The Center for Disease Control (CDC) has issued a statement recommending that the new vaccine be routinely given to girls when they are 11-12 years old since it is important that this vaccine be given prior to the onset of sexual activity (prior to potential exposure to the virus). However, they concur with the FDA indications that vaccination can start as early as 9 years old and up to the age of 26. Females within this age group who are sexually active may still benefit from the vaccine. The vaccine causes the body to produce a strong immune response creating antibodies. These antibodies when exposed to HPV 6, 11, 16, and 18 recognizes and attacks the HPV virus preventing the infection.

Currently, Gardasil is only approved for administration to females. Ongoing studies on the effect in males continue as well as additional studies to further evaluate the long-term effectiveness. 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.

Human papillomavirus (HPV) vaccine does not provide protection from all types of HPV. Routine Pap screening remains important for early detection of any abnormal changes in the cervix before cervical cancer can develop.

## Policy: Human Papillomavirus (HPV) Vaccine

### Evidence Based Guideline for Human Papillomavirus (HPV) Vaccine

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Human papillomavirus (HPV) vaccine (Gardasil) may be appropriate for girls and women who are between the age of 9 and 26. It is recommended that it be routinely given to girls 11-12 years old to reduce the risk of cervical cancer.

- Gardasil is given in three intramuscular injections over a 6 month period. The second dose should be given 2 months after the initial dose and the third dose should be administered 6 months after the first dose.
- Routine Pap screening remains important for early detection of any abnormal changes in the cervix before cervical cancer can develop.

### Medical Evidence regarding Human Papillomavirus (HPV) Vaccine indicates it is not recommended in the following situations:

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- When the criteria above are not met.
- It is not recommended to be given during pregnancy. If pregnancy is detected after the vaccine has been given the subsequent dosing should be delayed until the pregnancy has been completed. The company will be monitoring the outcomes of women who have had the vaccine in relation to subsequent pregnancies.

### Benefits Application

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Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 90649*

### Medical Term Definitions

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Not applicable

### Scientific Background and Reference Sources

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BCBSA TEC - Medical Policy Clearinghouse News [Electronic Version]. 5/26/2006

U.S. Food and Drug Administration (FDA). (2006, June 8). FDA licenses new vaccine for prevention of cervical cancer and other diseases in females caused by human papillomavirus. Retrieved 6/13/06 from <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>.

## **Policy: Human Papillomavirus (HPV) Vaccine**

CDC. (2006, June 29). CDC's Advisory Committee recommends human papillomavirus vaccination. Retrieved 7/12/06 from <http://www.cdc.gov/od/oc/media/pressrel/r060629.htm>.

National Cancer Institute (NCI). (2006). Statement from the National Cancer Institute on FDA approval of the HPV vaccine. Retrieved 7/13/2006 from <http://www.cancer.gov/newscenter/pressreleases/HPVStatement>

Specialty Matched Consultant Advisory Panel - 11/2006

### **Policy Implementation/Update Information**

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8/7/06 New policy issued.

12/11/06 Specialty Matched Consultant Advisory Panel review 11/6/2006. Medical Policy changed to Evidence Based Guideline. Wording changed in the "Evidence Based Guideline" section from "It is recommended that it be routinely given to girls, 11-12 years old as a preventive service against cervical cancer." to "It is recommended that it be routinely given to girls, 11-12 years old to reduce the risk of cervical cancer." References added.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.