

Evidence Based Guideline

Human Papillomavirus (HPV) Vaccine

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Description of Procedure or Service

Since the widespread use of the Pap test started in the 1970's, there has been a 50% decrease in the incidence of cervical cancer and 70% decrease in deaths resulting from cervical cancer among women in the United States. However, the disease remains a serious health threat. It is estimated that in 2010, 12,200 women in the United States will be diagnosed with cervical cancer and 4,210 women will die from the disease. The lifetime risk of cervical cancer would be an estimated 3.7% in the absence of cervical cancer screening. Researchers have worked 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. In June 2006, the U.S. Food and Drug Administration (FDA) 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) and Prevention has issued a statement recommending that the 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. The FDA has also recently expanded the uses for Gardasil® to include prevention of vaginal and vulvar cancer caused by the human papillomavirus type 16 and 18 for females ages 9-26 years old.

In October of 2009, the FDA approved the use of Gardasil® for males, ages 9 - 26 years to reduce the possibility of contracting genital warts. In October of 2011, the ACIP recommended a 3-dose series for HPV vaccine for males at age 11 or 12 years old.

Ongoing studies on the effect in males continue as well as additional studies to further evaluate the long-term effectiveness. 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. Use of the vaccine in older women (over 26 years) is also being evaluated.

On October 16, 2009, the FDA approved Cervarix® manufactured by GlaxoSmithKline Biologicals, a

Human Papillomavirus (HPV) Vaccine

vaccine to prevent cervical cancer and precancerous lesions caused by human papillomavirus (HPV) types 16 and 18. Its use is approved for females ages 10 - 25 years.

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.

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Evidence Based Guideline for Human Papillomavirus (HPV) Vaccine

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.

Human papillomavirus (HPV) Bivalent vaccine (Cervarix®) may be appropriate for girls and women who are between the age of 10 and 25.

- Cervarix® is given in three intramuscular injections over a 6 month period. The second dose should be given 1 month 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.

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

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

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. Both companies will be monitoring the outcomes of women who have had the vaccine in relation to subsequent pregnancies.

Benefits Application

This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this evidence

Human Papillomavirus (HPV) Vaccine

based guideline.

Billing/Coding/Physician Documentation Information

This evidence based guideline 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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 90649, 90650

Scientific Background and Reference Sources

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>.

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

U.S. Food and Drug Administration (FDA). (2008). FDA approves expanded uses for Gardasil to include preventing certain vulvar and vaginal cancers. Retrieved 9/15/2008 from <http://www.fda.gov/bbs/topics/NEWS01885.html>

Specialty Matched Consultant Advisory Panel - 11/2008

U.S. Food and Drug Administration (FDA). (2009). FDA approves new indication for Gardasil to prevent genital warts in men and boys. Retrieved 11/4/09 from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187003.htm>

U.S. Food and Drug Administration (FDA). (2009). FDA approves new vaccine for prevention of cervical cancer. Retrieved 11/4/09 from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187048.htm>

Advisory Committee on Immunization Practices (ACIP) Vaccines for Children Program. Vaccines to prevent human papilloma virus. Resolution No. 010/09-1. Adopted and effective 10/21/09. Retrieved from <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0608hvp.pdf>

Senior Medical Director Review - 11/2009

Specialty Matched Consultant Advisory Panel – 2/2012

Advisory Committee on Immunization Practices (ACIP) Vaccines for Children Program Vaccines to prevent human papilloma virus. Resolution No. 010/11-1. Retrieved from <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/10-11-1-hpv.pdf>

Human Papillomavirus (HPV) Vaccine

Policy Implementation/Update Information

- 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.
- 12/22/08 Specialty Matched Consultant Advisory Panel review 11/13/08. Revised "Description" section. "The FDA has also recently expanded the uses for Gardasil to include prevention of vaginal and vulvar cancer caused by the human papillomavirus type 16 and 18 for females ages 9-26 years old. References added. (btw)
- 12/21/09 Updated "Description" section to add new information regarding Gardasil® and Cervarix®. Also added FDA statement regarding use of Gardasil in males. "Evidence Based Guideline" added for the use of Cervarix®. CPT code 90650 added to the "Billing/Coding" section. (adn)
- 3/16/10 Specialty Matched Consultant Advisory Panel review 2/11/10. No change to policy statement.
- 6/22/10 Policy Guideline Number(s) removed (amw)
- 12/7/10 Added information regarding use of Gardasil in males from the "Description" section to the "Evidenced Based Guideline" section for clarity. Reviewed by medical director. (lpr)
- 3/29/11 Specialty Matched Consultant Advisory Panel review 2/23/11. No change to Guidelines. (adn)
- 3/20/12 Specialty Matched Consultant Advisory Panel review 2/29/12. Added "Human papillomavirus (HPV) vaccine (Gardasil®) may be appropriate for boys and men who are between the age of 9 and 26. It is recommended that it be routinely given to boys 11-12 years old to reduce the risk of anal cancer and genital warts. 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."

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.