


IN GOOD HEALTH

A Publication Compiled by the Clinical Pharmacy Team of  **Health Solutions**
PHARMACY BENEFITS MANAGEMENT

HUMAN PAPILLOMAVIRUS (HPV)

IHPV (human papillomavirus) is a group of viruses that infect the skin and mucous membranes. Over 100 strains of HPV have been identified, more than 30 of which are transmitted through sexual contact infecting the anal/genital region of both men and women. HPV is the most common sexually transmitted infection in the United States; it can be spread through vaginal, anal, and oral sex. It is estimated that approximately 50% of sexually active people will be infected with HPV at some time in their life, with 6.2 million new cases reported each year. By age 50, 80% of women will have had a genital HPV infection.


Some HPV infections present as visible genital warts on the vagina, cervix, vulva, penis, and rectum. These moist, pink flesh-colored swellings may be single or multiple, small or large, and may appear within a week to months after contact with a person who was infected, or not appear at all. Most genital HPV infections present with no symptoms and may clear on their own. Persistent infection with certain strains of HPV can eventually lead to cervical cancer in women, or cancer of the penis in men.

Women are usually diagnosed with HPV after an abnormal cervical Pap smear test. There is also a test that can be performed for women with mild pap abnormalities or those over the age of 30 that detects HPV DNA. The results may help physicians determine whether treatment or further testing is needed. All types of HPV can cause mild abnormalities in the Pap test, but only a subset of "high-risk" HPV strains may lead to the development of cervical cancer. Abnormal cells develop in the lining of the cervix. They may become precancerous, then cancerous over time. Women, who have persistent infections or a persistent infection with high-risk types of HPV are said to have the main risk factor for cervical cancer. In the US an average of 9710 new cases of cervical cancer occur each year, with an associated 3700 deaths occurring annually from this cancer.

To reduce the risk of genital HPV infection, the recommendation is to refrain from any genital contact with another individual, or to limit sexual activity to one long-term mutually monogamous uninfected partner. If this is not possible, limit the number of sexual partners. Latex condoms only provide partial protection against genital HPV infection because areas of genital skin not covered by the condom may be infected with HPV.

Gardasil ® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] is the first vaccine to help guard against the diseases caused by HPV. Gardasil is effective against HPV types 16 and 18 which cause 70% of cervical cancer cases, and types 6 and 11 which cause 90% of genital warts. Studies in the US and 3 multinational studies provided evidence of Gardasil being nearly 100% effective in preventing precancerous lesions (cervical, vaginal & vulvular) and genital warts in women (age 16-26, not previously infected) from the HPV types 6, 11, 16 and 18. Studies also showed the immune response in 9-15 year old females was as good as the 16-26 year old females with similar effectiveness expected from the vaccine. The FDA has licensed Gardasil for use in girls/women ages 9-26 years old. This vaccine is given through a series of 3 shots over a 6 month period of time. In 2006 the Advisory committee on Immunization

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Practices voted to recommend Gardasil® as routine immunization for the recommended age groups. Safety, long-term effectiveness, and pregnancy outcome studies are ongoing by the manufacturer, Merck & Co.

Commonly asked questions about Gardasil:

Who should get the HPV Vaccine?

Girls and young women 9-26 years of age.

Why is this vaccine recommended for young girls?

Ideally the vaccine is most effective in girls/women before they are sexually active. This population will not have been infected with the 4 types of HPV that this vaccine protects against.

Will sexually active females benefit from this vaccine?

This vaccine provides protection from 4 types of HPV. Few sexually active women are infected by all 4 types of HPV, so this vaccine will provide protection against the others.

Why is the vaccine only recommended for girls/women in the 9-26 age range?

This vaccine was widely tested in the 9-26 age group for safety and efficacy and approved by the FDA. Research in women older than 26 years is currently under study.

Should boys/men be vaccinated?

The vaccine is not approved for males. The effectiveness of the vaccine in preventing HPV infection and disease in males is currently being studied.

Can a pregnant woman receive the vaccine?

It is not recommended for pregnant women.

What is the efficacy?

Gardasil is 100% effective in reducing diseases caused by the 4 HPV types, including precancers of the cervix, vulva, and genital warts. It is less effective in girls/women already exposed to one of the HPV types. It does not treat existing HPV infections, genital warts, precancers, or cancer. It does not protect against other sexually transmitted diseases. Continuing studies will determine how long the vaccine will protect (currently-5 year efficacy) and if a booster will be needed in the future.

Safety?

It has been tested in 11,000 females around the world, and no serious side effects have been detected. The most commonly reported side effect was soreness at the injection site. This vaccine does not contain thimerosal or mercury, or infectious material.

Will cervical cancer screening still be needed?

Yes. The vaccine does not protect against all types of HPV, and if a woman was infected prior to the vaccine they may not have the full protection of the vaccine. Routine pap tests and other screenings are still recommended.