

**Immunization Program
Vaccines for Children Program
Human Papillomavirus (HPV) Vaccine
January 2010**

Updated recommendations for the use of human papillomavirus HPV vaccine for the quadrivalent HPV (types 6, 11, 16, and 18) vaccine, Gardasil, for females and males.

The purpose of this vaccine summary is to:

Allow permissive use of the quadrivalent HPV4 vaccine, Gardasil, for VFC-eligible males, 9 through 18 years of age.

Human Papillomavirus (HPV) Vaccine Recommendations

Food and Drug Administration (FDA)

- In June 2006, the FDA approved, Gardasil for females 9 through 26 years of age, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to HPV types 6, 11, 16 and 18.
- On October 16, 2009, the FDA approved the use of Gardasil in males.

ACIP - The ACIP workgroup recommended Gardasil for routine immunization of females 11 through 12 years of age. The vaccination series can be started in females as young as 9 years of age. The workgroup also recommends the vaccine for females 13 through 26 years of age who previously have not received the vaccine.

The ACIP recommended allowing permissive use of the quadrivalent HPV vaccine for VFC eligible males 9 through 18 years of age. In the general population, the 3-dose series of Gardasil may be given to males aged 9 through 26 years of age to reduce the likelihood of acquiring genital warts.

VFC Resolution - The ACIP workgroup updated recommendations for the use of HPV vaccine for VFC-eligible children to include:

Gardasil (HPV4) routine recommendation to vaccinate females 9-18 years of age and allow permissive use of the vaccine for males 9 through 18 years of age.

Permissive Recommendations for Males

The 3-dose series of quadrivalent (Gardasil) HPV4 vaccine may be given to males aged 9 through 18 years to reduce the likelihood of acquiring genital warts. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

The ACIP defines permissive use of HPV4 in males 9 through 18 years of ages to include:

- vaccinating based upon request
- may offer vaccine proactively

Permissive use does not indicate:

- the healthcare provider is expected to offer vaccine proactively
- vaccine uptake will not be used as a measure of provider performance

Recommended Schedule for HPV Vaccine

The quadrivalent HPV vaccine is administered in a 3-dose schedule:

- 1st dose:** Initial dose
- 2nd dose:** 2 months after the first dose
- 3rd dose:** 6 months after the first dose (12 weeks between dose 2 and 3, overall, there must be at least 24 weeks between doses 1 and 3)

HPV vaccine can be administered at the same visit when other age appropriate vaccines are provided, such as Tdap, Td and MCV4.

Syncope can occur after vaccination, most commonly among adolescents and young adults. To avoid serious injury related to a syncopal episode, vaccine providers should consider observing patients for 15 minutes after they are vaccinated.

Accelerated Schedule (Minimum Intervals) for HPV Vaccine

- Minimum Age 9 years
- Dose 1 to 2 4 weeks
- Dose 2 to 3 12 weeks (Overall, there must be at least 24 weeks between doses 1 and 3.)

VFC Catch-up Vaccination

Catch-up vaccination is recommended for females 13-18 years of age who have not been previously vaccinated or who have not completed the full series.

Interrupted Vaccine Schedules

If the vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be given as soon as possible separated by an interval of at least 4 weeks. The second and third doses should be separated by an interval of at least 12 weeks with a minimum interval of 24 weeks between the first and third doses. If only the third dose is delayed, it should be administered as soon as possible.

Recommended Dosage

Each dose of HPV vaccine is 0.5mL, administered intramuscularly. Refer to package insert.

Vaccine Storage and Handling

Store refrigerated at 2 to 8°C (35 to 46°F). Do not freeze. Protect from light. Refer to package insert.

Special Situations

Quadrivalent HPV vaccine can be given to females who have an equivocal or abnormal Pap test, a positive Hybrid Capture II ® high risk test, or genital warts.

Vaccine recipients should be advised that data from clinical trials do not indicate the vaccine will have any therapeutic effect on existing Pap test abnormalities, HPV infection or genital warts. Vaccination of these females would provide protection against infection with vaccine HPV types not already acquired.

Immunocompromised persons

HPV vaccine is not a live vaccine and can be administered to persons who are immunocompromised as a result of disease or medication; however, the immune response to the vaccine might be less than that in persons who are immunocompetent.

Vaccination during pregnancy

HPV vaccines are not recommended for use during pregnancy. The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination in pregnancy are limited. Until further information is available, initiation of the vaccine series should be delayed until after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccination series, completion of the 3-dose regimen should be delayed until after completion of the pregnancy. If a vaccine dose has been administered during pregnancy, there is no indication for any intervention. A vaccine in pregnancy registry has been established; patients and health-care providers are encouraged to report any exposure to quadrivalent HPV vaccine during pregnancy by calling (800) 986-8999 (Merck).

Lactating women

Lactating women can receive HPV vaccine.

Precautions and Contraindications

Acute illness

HPV vaccines can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory track infections, with or without fever). Vaccination of persons with moderate or severe acute illnesses should be deferred until after the illness improves.

Immediate hypersensitivity or allergy to vaccine components

Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to any vaccine component.

Vaccine Licensure / VFC Implementation

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee whose role is to provide advice and guidance regarding the most appropriate application of vaccines for effective vaccine preventable disease control. The Food and Drug Administration (FDA) is responsible for the licensure of vaccines. Upon FDA approval the ACIP convenes and makes decisions on vaccine recommendations. A VFC resolution vote is required for the inclusion of new vaccines into the VFC Program or the modification of existing resolutions. The Centers for Disease Control and Prevention (CDC) then negotiates a contract for the purchase of vaccines. This contract is normally finalized within three months. VFC vaccine must be administered according to the guidelines outlined by the ACIP recommendations and VFC resolutions.

CDC allocates individual state VFC funding based upon eligible populations, anticipated vaccine uptake and negotiated federal contract amounts. CDC establishes monthly vaccine allocations for each vaccine. Additional 317 CDC discretionary funds are used to vaccinate underinsured individuals seen at Local Public Health Agencies (LPHAs) who are not eligible under VFC guidelines. Each state determines the vaccine implementation date based upon the above process which is generally four to six months following vaccine licensure.

School Requirements

The role of school laws is to assist in the removal of barriers to vaccine and to prevent the transmission of disease in school settings. At this time IDPH is not pursuing school requirements for HPV vaccine.

IDPH/Immunization Program Recommendations

The IDPH, Immunization Program routinely follows and promotes the ACIP Recommended Immunization schedule. The Immunization Program is implementing HPV vaccine in accordance with the ACIP recommendations and the VFC resolution.

Gardasil CPT Code 90649