

**Immunization Program
Vaccines for Children Program
Human Papillomavirus (HPV) Vaccine Summary
December 2016**

Purpose of vaccine summary

- Updated Advisory Committee on Immunization Practices (ACIP) recommendations for the use of human papillomavirus (HPV) vaccine, December 16, 2016.
- Revised Iowa VFC Program recommendations for the use of HPV vaccine effective December 16, 2016.

Human Papillomavirus (HPV) Vaccine Recommendations

Food and Drug Administration (FDA)

- On October 7, 2016, the FDA approved Gardasil 9 to be used as a two-dose schedule for individuals 9 through 14 years of age.
- On December 14, 2015, the FDA expanded its approval for the use of Gardasil 9 in males 16 through 26 years of age.
- On December 10, 2014, the FDA approved Gardasil 9 for
 - females 9 through 26 years of age, to prevent cervical, vulvar, and anal cancers, precancerous genitoanal lesions and genital warts due to HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.
 - males 9 through 15 years of age to prevent anal cancer and precancerous lesions and genital warts due to HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.
- On October 16, 2009, the FDA approved Cervarix for use in females 10 through 25 years of age.
- On October 16, 2009, the FDA approved the use of Gardasil in males.
- In June 2006, the FDA approved, Gardasil for females 9 through 26 years of age, to prevent cervical cancer, precancerous genital lesions and genital warts due to HPV types 6, 11, 16 and 18.

Advisory Committee on Immunization Practices (ACIP)

- HPV is routinely recommended for adolescents at 11 or 12 years of age.
- The series may be started as young as 9 years of age. The series is also recommended for females 13 through 26 years of age and males 13 through 21 years of age who have not been vaccinated previously. Males 22 through 26 years of age may be vaccinated.
- Any brand may be given to females from 9 through 26 years of age.
- Gardasil and Gardasil 9 should be given to males 9 through 21 years of age and may be given to males 22 through 26 years of age. (Cervarix should not be used in males).
- Healthy adolescents who begin the HPV series between 9 through 14 years of age may complete the 2-dose series by administering the second dose at least 6 to 12 months after the first dose.
- Immunocompromised individuals 9 through 26 years of age should complete the 3-dose series at 0, 1-2, and 6 month intervals.

- Healthy adolescents and young adults who begin the series between 15 through 26 years of age should complete the 3-dose series at 0, 1-2, and 6 month intervals.

VFC Resolution

The VFC Program follows the ACIP recommendations for the use of HPV vaccine for VFC eligible children 9 through 18 years of age.

Recommended Schedule for HPV Vaccine

The 2-dose schedule should be administered to healthy adolescents who begin the HPV vaccine series between 9 through 14 years of age:

- 1st dose:** initial dose
- 2nd dose:** 6 to 12 months after the first dose

The 3-dose schedule should be administered to adolescents and young adults who begin the series between 15 through 26 years of age, and to immunocompromised individuals regardless of when they started the series:

- 1st dose:** initial dose
- 2nd dose:** 1 to 2 months after the first dose
- 3rd dose:** 6 months after the first dose, and at least 12 weeks after the second dose

HPV vaccine can be administered at the same visit as other routinely recommended adolescent vaccines such as Tdap, MCV4, meningococcal B, and influenza.

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.

Interrupted Vaccine Schedules

If the vaccine schedule is interrupted the vaccine series does not need to be restarted.

Minimum Intervals for HPV Vaccine

Minimum Age: 9 years

2-dose schedule

Dose 1 to 2: 5 calendar months

3-dose schedule

Dose 1 to 2: 4 weeks

Dose 2 to 3: 12 weeks

Overall, there must be at least 5 calendar months between doses 1 and 3.

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 (36 to 46°F). Do not freeze. Protect from light. Refer to package insert.

Special Situations

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 vaccine series 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. Merck has established a registry for women who receive HPV 9 vaccine in pregnancy; patients and health-care providers are encouraged to report any exposure to HPV 9 vaccine during pregnancy by calling (800) 986-8999.

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 tract 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

Bivalent and quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to any vaccine component. The prefilled syringes of bivalent HPV vaccine should not be used in persons with anaphylactic latex allergy because syringes have latex in the rubber stopper. Bivalent HPV vaccine single dose vials contain no latex.

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. HPV vaccine is not required for school enrollment.

HPV 9 CPT Code: 90651