

Quadrivalent HPV (HPV4, Gardasil®) & Bivalent HPV (HPV2, Cervarix™)

Table 1: Human Papillomavirus Vaccine Recommendations

Vaccine	HPV Types	Recommended for Females	Recommended for Males	Prevents
Quadrivalent HPV (HPV4, Gardasil®) <i>Merck</i>	6, 11, 16, & 18	Yes 11-26 yrs*	Yes 11-21 years*	Pre-cancers, cervical, vulvar, vaginal and anal cancers; genital warts
Bivalent HPV (HPV2, Cervarix™) <i>GlaxoSmithKline</i>	16 & 18	Yes 11-26 yrs*	No	Cervical cancer, pre-cancers

Human Papillomavirus Vaccine Recommendations

Females

- HPV4 (Gardasil®) and HPV2 (Cervarix™) vaccines recommended for routine vaccination of females aged 11-12 years at 0, 1-2 months, and 6 months (See Table 2). The 3-dose vaccination series can be started as early as 9 years of age.*
- Catch-up vaccination is recommended for females aged 13-26 years who have not been vaccinated or completed the 3-dose vaccination series.

Males

- HPV4 (Gardasil®) vaccine is recommended for routine vaccination for males aged 11-12 years for the prevention of anal cancer and genital warts at 0, 1-2 months, and 6 months (See Table 2). The 3-dose vaccination series can be started as early as 9 years of age.*
- Catch-up vaccination is recommended for males aged 13-21 years who have not been vaccinated or completed the 3-dose vaccination series.
- Males aged 22-26 years may be vaccinated.
- **HPV2 (Cervarix™) vaccine is not licensed for use in males.**

Special Populations

- Men who have sex with men (MSM) are at increased risk for conditions associated with HPV types 6, 11, 16, and 18 and have a higher incidence of disease and cancer including anal intraepithelial neoplasia (AIN), anal cancers, and genital warts.
- Persons who are immunocompromised as a result of infection (HIV), disease, or medications. The immune response and vaccine efficacy might be less than that of immunocompetent persons.
- For immunocompromised males, ACIP recommends routine vaccination with HPV4 and vaccination through age 26 years for those who have not been vaccinated or have not completed the 3-dose series (See Table 2).



Indications

HPV4 (Gardasil®)

- Gardasil is indicated for the prevention of pre-cancers, cervical, vulvar, and vaginal cancers (in females); anal cancer and genital warts (in females and males).
- Protects against 4 types of HPV: Types 16 and 18 which are responsible for 70% of cervical cancers and Types 6 and 11 which (along with 18) are responsible for 90% of genital warts.

HPV2 Vaccine (Cervarix™)

- Protects against two types of HPV: Types 16 and 18 which are responsible for 70% of cervical cancers.

Administration:

- Whenever possible, the same vaccine product should be used for all doses in the series. However, if providers do not know or have available the HPV product previously administered, either HPV vaccine product can be used to continue or complete the series and provide protection against HPV types 16 and 18.
- If fewer than 3 doses of HPV4 are received, protection against HPV types 6 and 11 may not be adequate to protect against genital warts. .
- HPV4 and HPV 2 can be used interchangeably in females. HPV2 is not recommended for use in males (See Table 1).
- If the HPV schedule is interrupted, the vaccine series does not need to be restarted.
- HPV vaccines are inactivated and can be administered simultaneously or anytime before or after an inactivated or live vaccine.
- HPV vaccine should be administered IM into the deltoid muscle.

Table 2: Human Papillomavirus Vaccination Schedule

Dose Number	Dosage	Route	Intervals
First	0.5 mL	IM	
Second	0.5 mL	IM	1-2 months after the first dose (A minimum of 4 weeks after the first dose)
Third	0.5 mL	IM	6 months after the first dose (At least 12 weeks after the second dose and at least 24 weeks after the first dose)

**Contraindications**

- Hypersensitivity such as a severe allergic reaction (e.g. anaphylaxis) after a previous dose of HPV vaccine or any vaccine component.
 - HPV2 (Cervarix™): the prefilled syringes contain latex
 - HPV4 (Gardasil®): contraindicated for persons with a history of immediate hypersensitivity to yeast
- HPV vaccines are not recommended for use in pregnant women; pregnancy testing is not needed before vaccination. Any exposure to an HPV vaccine during pregnancy should be reported to the appropriate vaccine pregnancy registry:
 - 1-800-986-8999 (Merck for Gardasil®)
 - 1-888-452-9622 (GlaxoSmithKline for Cervarix™)
- If a woman is found to be pregnant after initiating the HPV vaccine series, remaining doses should be delayed until after the pregnancy.

Precautions

- Syncope: Some people may develop syncope resulting in an injury from falling. Observe patients for 15 minutes after administering HPV vaccine.
- Moderate or severe illness.

Adverse Reactions

- **Injection site:** pain redness, swelling.
- **Systemic:** fatigue, headache, myalgia (muscle pain), gastrointestinal symptoms, arthralgia (joint pain), fainting (syncope), abdominal pain (HPV2).

Storage and Handling

- Store HPV vaccine in the refrigerator between 35°F – 46°F (aim for 40°F).
- **Do not freeze** - discard if vaccine is exposed to freezing temperatures (32°F or below)
- **Protect HPV4 (Gardasil®) from light.**

