

## Pharmacy Protocol

### 9-VALENT HUMAN PAPILLOMAVIRUS VACCINE: HPV9 (Gardasil® 9)

Last Reviewed	29 November 2022
Last Revised	29 November 2022
This order expires	30 November 2024

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### 1. What's new

Reviewed for changes and updates. No significant changes.

## 2. Oregon immunization pharmacy protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications.
- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for IM injection.
- F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.
- G. Give the 0.5-mL dose of HPV vaccine intramuscularly IM, preferably in the deltoid muscle.
- H. HPV may be given simultaneously with all routine adolescent or adult vaccines.
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.
- J. This order does **not** cover Advisory Committee on Immunization Practices (ACIP) recommendations that involve shared clinical decision making. Shared clinical decision making means the decision to vaccinate should be based on a discussion of benefits and risks between the patient and the clinician, and the clinician would then prescribe the vaccine.

I have read, understand, and agree to participate by the terms of this protocol.

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Immunizing Pharmacist

Date

### 3. Vaccine schedule for HPV9

Dose and Route: 0.5-mL IM <sup>1</sup>				
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing	Recommended spacing
2-dose series: <b>Healthy</b> persons who begin the HPV series before their 15 <sup>th</sup> birthday may complete the series with 2 doses. <sup>3</sup>				
1	11 to 12 years	9 years		
2			5 months after dose 1	6–12 months after dose 1
Immunocompromised persons and catch-up for persons beginning the series ≥15 years of age need 3-doses. <sup>3</sup> See § 5, Recommendations for use below.				

### 4. Licensed HPV9 vaccine<sup>1</sup>

Human Papillomavirus 9-Valent		
Trade Name	Presentation	Acceptable age range
Gardasil® 9	0.5-mL single dose vials	9–26 years*
	0.5-mL prefilled syringes	

\*27–45 years by prescription only.

### 5. Recommendations for use<sup>3</sup>

Routine HPV9 Vaccine healthy* children, initiated before 15 years of age				
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing	Recommended Spacing
1	11 years	9 years		
2			5 months after dose 1	6–12 months after dose 1

HPV9 Vaccine for immunosuppressed patients* <u>or</u> catch-up initiated at or after 15 years of age			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	11–15 years	9 years	
2			4 weeks after dose 1
3			3 months after dose 2 <b>and</b> 5 months after dose 1

\* A 3-dose series should be administered to persons with primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity, such as B-lymphocyte or antibody deficiencies, complete or partial T-lymphocyte defects, HIV infection, malignant neoplasm, transplantation, autoimmune disease, or immunosuppressive therapy.

## 6. Contraindications<sup>1</sup>

- A. Hypersensitivity to any vaccine component
- B. Hypersensitivity to yeast
- C. Pregnancy: HPV vaccines should not be administered during pregnancy. Exposure during pregnancy can be reported to the Merck Pregnancy Registry at 1-800-986-8999.

## 7. Warnings and precautions<sup>6</sup>

- A. Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.
- B. Syncope after immunization is common among adolescents. Have the client sit for 15 minutes after vaccination.

## 8. Other considerations

- A. **Adverse Events:** Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case

of anaphylactic or acute hypersensitivity reaction.<sup>6</sup>

- B. **Lactation:** Nursing women can receive HPV vaccine.<sup>5</sup>
- C. Individuals with altered immunocompetence may have reduced immune responses.<sup>6</sup>
- D. Cervical cancer screening should be initiated at 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.<sup>4</sup>
- E. Women with an equivocal or abnormal pap test, positive Hybrid Capture II<sup>®</sup> high-risk test or genital warts can receive HPV vaccine. Recipients should be advised that the vaccine has no therapeutic value and will only provide protection against infection with HPV types not already acquired.<sup>5</sup>

## 9. Side effects and adverse reactions<sup>1</sup>

Injection Site Reactions	
Pain, redness or swelling at vaccination site	Up to 90%
Systemic Adverse Reactions	
Low-grade fever of up to 101°F	Up to 10%
Fever of 102°F or more	Up to 1.5%

## 10. Storage and handling<sup>1</sup>

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Gardasil <sup>®</sup> 9	Store at 2°–8°C (36° to 46°F)	Do not freeze, protect from light	Administer as soon as possible after being removed from refrigeration

## 11. Adverse events reporting<sup>6</sup>

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>.

VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days)

## Event and interval from vaccination

- B. Shoulder Injury Related to Vaccine Administration (7 days)
- C. Vasovagal syncope (7 days)
- D. Any acute complication or sequelae (including death) of above events (interval - not applicable)
- E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert).

## 12. References

1. Merck and Company, HPV 9 (Gardasil<sup>®</sup>9) 2014 package insert. Available at: [www.merck.com/product/usa/pi\\_circulars/g/gardasil\\_9/gardasil\\_9\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf). Accessed 9 November 2022.
2. Meites E, Szilagyi PG, Chesson HW, Unger ER, Romero JR, Markowitz LE. Human papillomavirus vaccination for adults: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2019; 68:698–702. Available at: [www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf](http://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf) Accessed 9 November 2022.
3. Meites E, Kempe A, Markowitz LE. Use of a 2-dose schedule for human papillomavirus vaccination: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2016; 65:1405–8. Available at: [www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf](http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf) Accessed 9 November 2022.
4. Petrosky E, Bocchini JA, Hariri S, Chesson H, Curtis CR, Saraiya M, et al. Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the Advisory Committee on Immunization Practices. MMWR 2015; 64:300–4. Available at: [www.cdc.gov/mmwr/pdf/wk/mm6411.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf) Accessed 9 November 2022.
5. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63(RR05). Available at: [www.cdc.gov/mmwr/pdf/rr/rr6305.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf) Accessed 9 November 2022.
6. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practices Guidelines for Immunization. Available at: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf) Accessed 9 November 2022.

To request this material in an alternative format (e.g., Braille) or to clarify any part of

the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: [standing orders](#)

Electronic copy of this pharmacy protocol is available at: [protocols](#)