Immunization Protocol

Recombinant Herpes Zoster Vaccine RZV (Shingrix®)	
Last Reviewed	26 February 2024
Last Revised	26 February 2024
This order expires	28 February 2026

Table of contents

1. What's new

No substantive changes.

2. Oregon immunization 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. Counsel patients regarding expected reactogenicity (potential fever, chills, fatigue, muscle pain and headache) before administering vaccine. Encourage patients to complete the series even if they experience a significant reaction to the first dose.

E. Verify needle length for IM injection.

F. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.

G. Record all required data elements in the client's permanent health record.

H. May be given with all ACIP-recommended adult vaccinations.

I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

J. Ensure epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for Recombinant Herpes Zoster

Dose and Route - 0.5 mL IM[2,3]			
Dose	**Minimum acceptable age**	**Preferred Spacing**	**Minimum acceptable spacing**
1	≥ 19 years of age		
2		2–6 months	28 days

4. Licensed Recombinant Herpes Zoster Vaccine[3]

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
Shingrix	Varicella zoster virus	Single-dose antigen and adjuvant component vials combined for 0.5-mL dose	≥19 years of age	No

5. Recommendations for use[1-3]

A. RZV is routinely recommended for the prevention of herpes zoster (shingles) and related complications for immunocompetent adults aged 50 years and older and does not require pre-screening for varicella (chickenpox) in this age group (persons born in the United States before 1980 are presumed to have had varicella).

B. Immunocompromised adults aged 19 years and older should receive a two-dose series of RZV. Screening for antibodies to varicella-zoster virus may be needed.

C. Persons known to be not immune to varicella zoster virus should receive varicella vaccine, not RZV. See the OHA varicella immunization protocol for immunity determination and schedule information. Additional information can be found here: CDC Clinical Considerations for Use of Recombinant Zoster Vaccine (RZV, Shingrix) in Immunocompromised Adults Aged ≥19 Years.

D. The ACIP recommends use of RZV in persons taking low-dose immunosuppressive therapy (e.g., <20 mg/day of prednisone or equivalent or using inhaled or topical steroids), persons anticipating immunosuppression, or people who have recovered from immunocompromising illness. ACIP has not issued recommendations for persons on moderate or high dose immunosuppressive therapy.

E. Persons previously vaccinated with live zoster vaccine (Zostavax) should be revaccinated with RZV.

F. Persons with a history of herpes zoster should receive RZV. Patients currently experiencing an episode of zoster should wait to be vaccinated until the acute stage of the illness is over and symptoms have abated.

G. Persons with chronic medical conditions (e.g., diabetes mellitus, chronic renal failure, rheumatoid arthritis, and chronic pulmonary disease) should receive RZV.

6. Contraindications[1]

Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Vaccine Excipient Summary[5]
Shingrix	Sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-O-desacl4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract *Quillaja saponaria* Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA.

7. Warnings and precautions[1,3]

A. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should not be administered during an acute episode of herpes zoster.

B. There is currently no ACIP recommendation for RZV use during pregnancy. Providers should consider delaying RZV until after pregnancy.

C. In an observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following RZV vaccination.

8. Other considerations[1-3]

A. Recombinant vaccines such as RZV may be given to breastfeeding women and pose no known risk to the mother or infant.

B. Antiviral therapy, such as acyclovir, may be given concurrently with RZV.

C. The RZV adjuvant solution may contain up to 0.75 mL of liquid. The entire volume of the adjuvant solution should be withdrawn and used to reconstitute the lyophilized RZV vaccine. After mixing, withdraw the recommended dose of 0.5 mL and discard remainder.

9. Side effects and adverse reactions[2]

Adverse Event*	Frequency
Injection site events (pain at the injection site, redness, swelling)	Up to 78%
Systemic events (fatigue, headache, muscle ache, fever)	Up to 45%
Gastrointestinal	Up to 17%
Serious adverse events	Up to 2% (similar to placebo group)

*Approximately 17% of recipients will experience an adverse reaction that may disrupt activities of daily living and last up to 3 days.

10. Storage and handling[1]

All clinics who receive state-supplied vaccines must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temperature	Storage Issues	Notes
Shingrix[3]	2°–8°C (36°–46°F)	Protect vials from light. Do not freeze.	Discard reconstituted vaccine if not used within 6 hours.

		Discard if the adjuvant suspension or antigen component has been frozen.	

11. Adverse events reporting

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/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days) B. Varicella vaccine-strain viral reactivation (time interval unlimited) C. Shoulder injury related to vaccine administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

12. References

1. Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. MMWR 2018;67:103–8. Available at: www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6703a5-H.pdf. Accessed 25 February 2024.
2. Anderson TC, Masters NB, Guo A, et al. Use of recombinant zoster vaccine in immunocompromised adults aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2022;71:80–4. Available at: www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7103a2-H.pdf. Accessed 25 February 2024.
3. Shingrix® package insert (Revised 2023). Available at: www.fda.gov/media/108597/download. Accessed 25 February 2024.
4. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 25 February 2024.
5. Vaccine Excipient Summary. Available at:

www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 25 February 2024.

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 protocol is available at: Model Immunization Protocols