Immunization Pharmacy Protocol

Recombinant Herpes Zoster Vaccine RZV (SHINGRIX®)	
Last Reviewed	11 February 2022
Last Revised	11 February 2022
This order expires	29 February 2024

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1. What's new

New recommendation for zoster vaccine in immunocompromised adults ≥19 years of age.

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.

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

Pharmacist Signature Date

3. Vaccine schedule for Recombinant Herpes Zoster

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

4. Licensed Recombinant Herpes Zoster Vaccine

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
SHINGRIX[3]	Varicella zoster virus	0.5 mL single-dose vials	≥19 years of age	No

5. Recommendations for use[1]

A. RZV is routinely recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older and does not require pre-screening for chickenpox (varicella).

B. Immunocompromised adults aged 19 years and older should receive a two-dose series of RZV.[2]

C. Persons previously vaccinated with live zoster vaccine (Zostavax) should be revaccinated with RZV. Studies evaluated safety and immunogenicity ≥ 5 years after receipt of live zoster vaccine. Per ACIP, RZV should not be given < 2 months after live zoster vaccine.

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

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

F. ACIP recommends using 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.

G. Persons known to be VZV negative should receive varicella vaccine, not RZV. See the varicella immunization protocol for schedule information. vaccination.

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

A. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should

not be administered during an acute episode of herpes zoster.[1]

B. There is currently no ACIP recommendation for RZV use during pregnancy.[1] Providers should consider delaying RZV until after pregnancy.
C. In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following RZV vaccination.[3]

8. Other considerations

A. Recombinant vaccines such as RZV may be given to breastfeeding women and pose no known risk to the mother or infant.[2]

B. Antiviral therapy, such as acyclovir, may be given concurrently with RZV.[1]

B. 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. Any reconstituted vaccine left in the vial should be discarded.[3]

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

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	Temperature	Storage Issues	Notes
SHINGRIX[3]	2°–8°C (36°–46°F)	Protect vials from light. Do not freeze. Discard if the adjuvant suspension or antigen component has been frozen.	Discard reconstituted vaccine if not used within 6 hours.

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)

A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290.

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 January 2022
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 January 2022.
3. Shingrix® package insert (2021). Available at: www.fda.gov/media/108597/download. Accessed 25 January 2022.
4. Kroger A, Bahta L, Hunter 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 22 September 2021.

5. Vaccine Excipient Summary. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 22 September 2021.

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

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