OREGON HEALTH AUTHORITY
IMMUNIZING PHARMACIST PROTOCOL

Herpes Zoster Subunit Vaccine RZV (Shingrix®)[1]	
Last Reviewed	26 March 2019
Last Revised	26 March 2019
This order expires	31 July 2021

No change from the previous version.

OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Provide a current Vaccine Information Statement (VIS) and answer any questions.
3. Record all required data elements in the client's permanent health record.
4. Screen **clients ≥50 years** of age for contraindications to RZV vaccine.
5. **Counsel patients about expected reactogenicity before administering** Shingrix: potential fever, chills, fatigue, muscle pain, and headache as this may interrupt activities of daily living (ADL) for 2–3 days. Encourage patients to complete the series even if they experienced a grade 1-3 reaction to the first dose of Shingrix as it does not necessarily mean they will have a reaction to the second dose.[1]
6. Verify needle length for IM injection.
7. Avoid injecting in the upper third of the deltoid muscle.
8. Both client and vaccinator must be seated for vaccine administration.
9. See appendix for reconstitution directions. Do not give if vaccine has been frozen.
10. Administer 0.5mL Shingrix® vaccine **IM** into the deltoid to eligible patients. Avoid injecting into the upper third of deltoid muscle.
    See section II for footnotes
11. May give RZV (Shingrix®) concurrently with inactivated, non-adjuvanted influenza vaccine.
12. Antiviral therapy, such as acyclovir, may be given concurrently with RZV (Shingrix®).[4]
13. Ask client to <u>remain seated</u> on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

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Signature Immunizing Pharmacist Date

II. Table 1. VACCINE SCHEDULE

SHINGRIX® Dose and Route: 0.5 mL IM[1]			
Dose**	**Recommended age**	**Preferred Spacing**	**Minimal Acceptable Spacing**
1	≥50 years of age	≥8 weeks after zoster vaccine live (ZVL; Zostavax®) for patients ≥70 years of age* ≥5 years after ZVL for patients <70 years of age	≥8 weeks after ZVL*
2‡		2–6 months◊	28 days from dose 1 to 2 4-day rule does **not** apply [per OIP Medical Director] **§**

***** Based on expert opinion, RZV should not be given <2 months after receipt of ZVL (Zostavax®).
◊The vaccine series need **not** be restarted if more than 6 months have elapsed since the first dose. Individuals might remain at risk during a longer than recommended interval between doses 1 and 2.
§If the second dose of RZV is given less than 28 days after the first, the second dose **should be repeated.** The repeat dose should be spaced after the invalid dose by the recommended minimum interval (28 days). [4]
‡Do not use Zostavax to complete the Shingrix series.
** The RZV (Shingrix) 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. See Appendix.

III. Table 2. LICENSED VACCINE[1, 2]

LICENSED SINGLE-ANTIGEN VARICELLA ZOSTER VACCINE				
Product Name	**Varicella Zoster virus antigen component**	**Vaccine Components◊**	**Acceptable / Recommended Age Range**	**Thimerosal or Latex**
Shingrix®	50 mcg of the recombinant gE antigen	Reconstituted with adjuvant AS01B producing 50 mcg of MPL, 50 mcg of QS-21	≥50 years of age	No

IV. RECOMMENDATIONS FOR SHINGRIX®[1]

1. RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older and does not require screening for chickenpox (varicella).
2. RZV is preferred over ZVL for the prevention of herpes zoster and related complications.
3. ZVL remains a recommended vaccine for prevention of herpes zoster in immunocompetent adults aged ≥60 years of age.
4. Care should be taken not to confuse ZVL, which is stored in the freezer and administered subcutaneously, with RZV, which is stored in the refrigerator and administered intramuscularly.
5. RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received ZVL.
6. RZV is **not** indicated for the prevention of primary varicella infection (chickenpox).

V. CONTRAINDICATIONS: Shingrix® [2]

Allergies to RZV a history of anaphylactic reaction (hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) to the vaccine or an excipient of the vaccine. RZV does not contain preservatives. The vial stoppers are not made with natural rubber latex.

VI. A. PRECAUTIONS:[2]

1. Pregnancy/ Lactation: Consider delaying vaccination with RZV in such circumstances.
2. RZV does not have a pregnancy registry at this time.
3. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should not be administered during an acute episode of herpes zoster.

VI. B. DATA NOT AVAILABLE TO ASSESS:[1]

1. RZV has not be evaluated in persons who are VZV seronegative
2. Carcinogenesis, Mutagenesis
3. Pediatric use
4. Evaluation of administration of RZV with 23-valent pneumococcal polysaccharide (Pneumovax® 23) vaccine and Tdap (Boostrix®) is ongoing. The safety and efficacy of administration of two adjuvanted vaccines (e.g., RZV and adjuvanted influenza vaccine [Fluad]), either concomitantly or at other intervals have not been evaluated.

VII. OTHER CONSIDERATIONS[1]

1. **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.[1]
2. **Immunocompromised**: As with ZVL, the ACIP recommends the 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) and persons anticipating immunosuppression or who have recovered from an immunocompromising illness.
3. **Persons with a history of herpes zoster:** Herpes zoster can recur. Adults with a history of herpes zoster should receive RZV. If a patient is experiencing an episode of herpes zoster, vaccination should be delayed until the acute stage of the illness is over and symptoms abate. Studies of the safety and immunogenicity of RZV in this population are ongoing.
4. **Persons known to be VZV negative:** Screening for a history of varicella (either verbally or via laboratory serology) before vaccination for herpes zoster is not recommended. However, in persons known to be VZV negative via serologic testing, ACIP guidelines for varicella vaccination should be followed.
5. **Persons with chronic medical conditions:** Adults with chronic medical conditions (e.g., chronic renal failure, diabetes mellitus, rheumatoid arthritis, and chronic pulmonary disease) should receive RZV.

VIII. Table 3. Shingrix®: Percent of subjects with solicited local adverse reactions and general adverse event within 7 days of vaccination in adults aged 50-59 years, 60-69 years, and 70 years and older. Excluded, among others, subjects who were immunocompromised, had a history of previous HZ and who were vaccinated against varicella or HZ.

	Shingrix®	Placebo Normal Saline	Shingrix®	Placebo Normal Saline	Shingrix®	Placebo Normal Saline
Number followed for Safety	N =1315	N=1312	N=1311	N=1305	N=2258	N=2263
Age in Years	50–59		60–69		≥70	
Adverse Events:	Percent with Adverse Reactions*					
Local Reaction, Injection site						
Pain – Tenderness	88.4	14.4	82.8	11.1	69.2	8.8
Redness	38.7	1.2	38.4	1.6	37.7	1.2
Swelling	30.5	0.8	26.5	1.0	23.0	1.1
Headache	50.6	21.6	39.6	15.6	29.0	11.8
Myalgia	56.9	15.2	49.0	11.2	35.1	9.9
Fatigue	57.0	19.8	45.7	16.8	36.6	14.4
Shivering	35.8	7.4	30.3	5.7	19.5	4.9
Fever 99.5°F–100.4°F	27.8	3.0	23.9	3.4	14.3	2.7
Fever ≥102.2°F (preventing normal activity)	0.4	0.2	0.5	0.2	0.1	0.1
Gastrointestinal	24.3	10.7	16.7	8.7	13.5	7.6

* **~17% of clients will experience an adverse reaction that might disrupt ADL and last up to 3 days. These include local and general adverse reactions in subjects aged 50 years and older: pain (78.0%), redness (38.1%), and swelling (25.9%), myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).[1, 2]**

Source: Table 1, page 4 of Shingrix® package insert.

IX. Table 4. STORAGE AND HANDLING[2]

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	Latex	Temp	Storage Issues*	Notes
Shingrix®	None	2–8°C (36–46°F)	• **Do not freeze.** • **Protect both vials from light.**	• Discard if antigen suspension or adjuvant component has been frozen. • Use immediately after reconstitution, or store reconstituted vaccine at 2–8°C. • Discard vaccine if not used within 6 hours of reconstitution.

X. ADVERSE EVENTS REPORTING

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html

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-(2)(3). [5]

Electronic copy of this standing order is available at:
1.usa.gov/PharmacyImmunizationProtocols

Table 5. VAERS Reporting Table for all Varicella-Containing Vaccines: 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. Disseminated varicella vaccine-strain viral disease. o Vaccine-strain virus identified (time interval unlimited) o If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (time interval unlimited) D. Shoulder Injury Related to Vaccine Administration (7 days) E. Vasovagal syncope (7 days) F. Any acute complication or sequelae (including death) of above events (interval - not applicable) G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.

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 pharmacy protocol is available at:
1.usa.gov/PharmacyImmunizationProtocols

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 Morb Mortal Wkly Rep 2018;67:103–108. DOI: http://dx.doi.org/10.15585/mmwr.mm6703a5. Accessed 25 March 2019.

2. Shingrix® package insert (2017). Available at: https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM581605.pdf Accessed 25 March 2019.

3. Nair, N. Update on SIRVA Advisory Committee on Immunization Practices. Presentation slides 1–6. October 2017. Available by request at: acip@cdc.gov Accessed 25 March 2019.

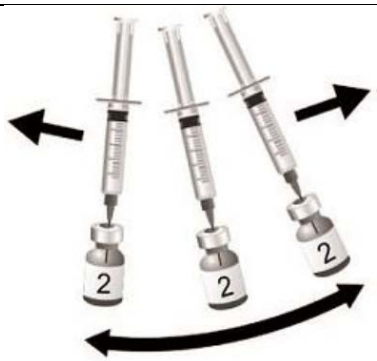
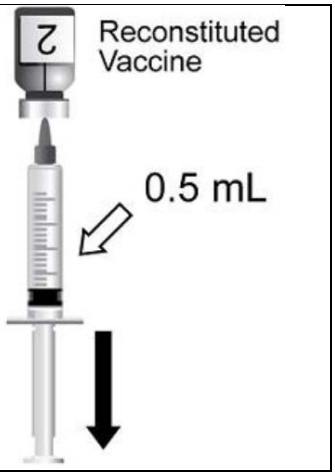
4. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html Accessed 25 March 2019.

5. Oregon Secretary of the State. Board of Pharmacy, Chapter 855; Division 19; Licensing of Pharmacists. OAR 855-019-0270, 0280, and 0290. Available at: https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3967 Accessed 25 March 2019.

APPENDIX

Reconstitution:

Prepare SHINGRIX by reconstituting the lyophilized varicella zoster virus glycoprotein E (gE) antigen component with the accompanying AS01B adjuvant suspension component. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

			
Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component by slightly tilting the vial (blue-green cap). Vial 1 of 2.	**Figure 2.** Slowly transfer entire contents of syringe into the lyophilized gE antigen component vial (brown cap). Vial 2 of 2.	**Figure 3.** Gently shake the vial to thoroughly mix contents until powder is completely dissolved.	**Figure 4.** After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer **intramuscularly**.