Zoster Vaccine Protocol for Adults

NAME AND STRENGTH OF VACCINE TO BE USED

Vaccine name	Age group	Dosage	Number of doses	Route of Admin.
Zoster Vaccine Recombinant, Adjuvanted (RZV, Shingrix®)	19 years and older who are or will be immunodeficient or immunosuppressed due to disease or therapy*	0.5 mL	2	IM
	50 years and older			

* Based on *Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices—United States, 2022*, MMWR 1.21.22)

INTENDED AUDIENCE AND PATIENT POPULATION

(1) Adults 19 years and older who are or will be immunodeficient or immunosuppressed because of disease or therapy

(2) Adults 50 years and older

PRECAUTIONS AND CONTRAINDICATIONS

(1) Shingrix is **contraindicated** in persons with a history of severe allergic reaction to any component of the vaccine or after a previous dose of Shingrix.

(2) There is no ACIP recommendation for RZV use in pregnancy. Providers should consider delaying RZV administration until after pregnancy. Clinicians may consider vaccination without regard to breastfeeding status if RZV is otherwise indicated.

(3) The zoster vaccine should not be administered in children or adolescents aged <19 years.

(4) When possible, patients should be vaccinated before becoming immunosuppressed. Otherwise, providers should consider timing the vaccine when the immune response is likely to be most robust (i.e., during periods of lower immunosuppression and stable disease).

(5) A zoster vaccine is not indicated for prevention of primary varicella infection (chickenpox) or for treatment of herpes zoster outbreak or postherpetic neuralgia. Zoster vaccine should not be administered during an acute episode of herpes zoster.

(6) Deferral of zoster vaccine should be considered in moderate or severe acute illness, for example, in the presence of fever.

SIDE EFFECTS AND ADVERSE REACTIONS

(A) Local reactions: erythema, pain/tenderness, swelling at the injection site usually of less than 48 hours duration occurs commonly: hematoma, pruritus, and injection-site warmth occur less commonly.

(B) General reactions: fever, myalgia, fatigue, headache, respiratory infection, diarrhea, rhinitis, skin disorder, respiratory disorder, asthenia, non-injection-site zoster-like rashes

Reactions of greater severity such as congestive heart failure, pulmonary edema, asthma exacerbation, and polymyalgia rheumatica have been reported. Goodpasture's syndrome and anaphylactic reaction were also reported. Rarely, death has been reported.

ADMINISTRATION

(A) Shingrix (RZV) Schedule:

Adults ≥50 years old: **Two doses given at 0 and 2-6 months**. Two doses are necessary regardless of prior history of herpes zoster or prior receipt of Zostavax (ZVL). RZV should not be given < 2 months after receipt of ZVL.

For persons who are or will be immunodeficient or immunosuppressed and who would benefit from a shorter vaccination schedule: Two doses given at 0 and 1-2 months. If the 2nd dose is administered <4 weeks after 1st dose, then a valid second dose should be repeated at least 4 weeks after the dose.

Note: The series does **not** need to be restarted if >6 months have elapsed since the first dose.

(B) Procedures

(1) Patient or legal guardian must first sign a consent form before the vaccination is administered.

(2) Provide a patient/ legal guardian with a copy of the most current federal Vaccine Information Statement (VIS) for zoster vaccine.

(3) **Shingrix vaccine**

(a) Vaccine is stored in the refrigerator between 2º and 8ºC (36º and 46ºF).

(b) To reconstitute the vaccine: Withdraw the entire contents of the vial (blue-green cap) containing the adjuvant suspension component into a sterile syringe. Slowly transfer entire contents of syringe into the lyophilized gE antigen component vial (brown cap). Gently shake the vial to thoroughly mix contents. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid.

(c) Inject 0.5 mL of reconstituted vaccine intramuscularly in deltoid region of the upper arm.

(d) Vaccine should be administered immediately after reconstitution or refrigerated between 2º and 8ºC (36º and 46ºF). Discard reconstituted vaccine if it is not used within 6 hours.

(C) Monitoring parameters

(1) Patients who faint should be placed supine. Check their pulse and blood pressure immediately.

(2) Watch for rapidly falling blood pressure, difficulty breathing, and sustained unconsciousness. Observe for adequate airway and pulse; administer CPR if needed. Have another member of the pharmacy staff call 911. Follow procedures in the next section for treatment of severe allergic/anaphylactic reactions.

(3) Treat externally for shock. Keep the patient warm, head low and feet elevated.

(4) Contact protocol physician as soon as possible to report the condition of the patient.

PROTOCOL FOR MANAGEMENT OF SEVERE ALLERGIC/ANAPHYLACTIC REACTIONS

(A) Pre-Vaccination Procedures
(1) Be prepared to call 911.
(2) Take a thorough history for allergies and prior adverse events before any immunization.
(3) Allow adequate physical space for fainting or collapse without injury and to lay the patient flat on a hard surface in the event CPR is needed.
(4) Maintain current competency in vaccine administration and in cardiopulmonary resuscitation; observe all vaccinees for at least 10 minutes after immunization; remind vaccinees to report any adverse events to you.

(B) Supplies to Stock
(1) Epinephrine USP, 1 mg/ml (1:1000). May be in vials of solution, *Ana-Guard* syringes, or in an *Epi-Pen*. At least three adult doses of epinephrine will be available wherever immunizations are given.
(2) Diphenhydramine liquid and injection.
(3) Blood-pressure cuff, adult size, with stethoscope.

(C) Recognition of Anaphylactic Reaction
(1) Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.
(2) Angioedema (swelling of the lips, face, throat)
(3) Bronchospasm

(D) Emergency treatment
(1) If itching and swelling are confined to the extremity where the immunization was given, observe the patient closely for a suitable period of time, watching for generalized symptoms. If none occur, go to paragraph D (8).

(2) If symptoms are generalized, activate the emergency medical system (EMS). Call 911 **and** the protocol physician for instruction. This should be done by a second person, while the immunizer treats and observes the patient.

(3) Administer epinephrine IM (refer to dosing chart). Standard dose is 0.01mg/kg up to 0.5 mg maximum in adults. Site of administration can be the anterolateral thigh if using auto-injector, or deltoid muscle above the vaccine injection site.

(4) Administer diphenhydramine by IM injection (refer to dosing chart). DO NOT administer diphenhydramine or any other drug by mouth if the patient is not fully alert or if the patient has respiratory distress.

(5) Monitor the patient closely until EMS arrives. Perform CPR and maintain airway, if necessary. Keep the patient in a supine position unless they are having breathing difficulty. If breathing is difficult, the patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. Monitor vital signs frequently.

(6) If EMS has not arrived and symptoms still persist, repeat dose of epinephrine every 10-20 minutes for up to 3 doses, depending on patient response.

(7) Record all vital signs, medications administered to the patient, including the time, dosage, response, and other relevant clinical information.

(8) Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later. After the event is concluded, complete a VAERS form. Report forms may be obtained online at www.vaers.hhs.gov or by calling 1-800-822-7967.

Suggested Dosing of Epinephrine and Diphenhydramine

Age Group Dose	**Weight * in kg**	**Weight * in lbs**	**Epinephrine Dose** 1 mg/mL injectable (1:1000 dilution) intramuscular	**Diphenhydramine (Benadryl)** 12.5 mg/5 mL liquid 25 and 50 mg capsules or tablets 50 mg/mL injectable
1-6 mos	4-7 kg	9-15 lbs	0.05 mg (0.05 ml)	5 mg
7- 18 mos	7-11 kg	15-24 lbs	0.1 mg (0.1 ml)	10 mg
19-36 mos	11-14 kg	24-31 lbs	0.15 mg (0.15 ml)	15 mg
37-48 mos	14-17 kg	31-37 lbs	0.15 mg (0.15 ml)	20 mg
49-59 mos	17-19 kg	37-42 lbs	0.2 mg (0.2 ml)	
5-7 yrs	19-23 kg	42-51 lbs	0.2 mg (0.2 ml)	30 mg
8-10 yrs	23-35 kg	51-77 lbs	0.3 mg (0.3 ml)	
11-12 yrs	35-45 kg	77-99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50-100 mg

*Dosing by body weight is preferred

ACCIDENTAL NEEDLE STICK

(A) Procedures

(1) Wash needle stick site with soap and water.

(2) Report the exposure to the physician on the protocol. Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and it should be started as soon as possible. **The National Clinicians' Post Exposure Prophylaxis Hotline (PEPline) has current recommendations (888.448.4911).**

(3) Discuss risks of acquiring HBV, HCV, HIV and the need for post-exposure treatment with the provider managing your exposure.

(4) Person giving the vaccination should already have received the Hepatitis B vaccine (extremely safe and effective).

(5) Follow-up testing should be available to all workers concerned about possible infection through occupational exposure.

(B) Treatment of Exposure

HCV – No treatment available

HBV – Post-exposure treatment of HBV is highly effective in preventing infection. Treat exposure as soon as possible after exposure, preferably within 24 hours and no later than 7 days after exposure. Hepatitis B vaccine and hepatitis B immune globulin (HBIG) are both approved for treatment use. If any symptoms suggesting HBV infection develop, patient should contact a physician.

HIV - Start as soon as possible, ideally within 72 hours of exposure. Benefit of treatment delayed beyond 72 hours is not defined. No medications are FDA-approved for prevention. Pharmacist will follow current HIV prevention guidelines recommended by CDC. Truvada® (emtricitabine and tenofovir disoproxil fumarate) plus Isentress® (raltegravir) OR Truvada® plus Tivicay® (dolutegravir) are recommended for 28 days with repeated testing to confirm HIV negative status.

(C) Precautions During Follow-Up

HBV – no precaution recommended.

HCV – low risk, so no precautions are recommended.

HIV – 6-12 weeks is when most of the signs and symptoms of infection show. Do not donate blood, semen, or organs during this time. Do not have sexual intercourse during this time, or else use a condom consistently and correctly. Women should not breast feed. HIV is transmitted through breast milk.

(See page 6 for Physician Authorization)

Administration of the zoster vaccine, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____
_____ _____ _____

Administration of the zoster vaccine, under the direction of the physician who signed below, may be performed at the following location(s) including street address(es):

_____

_____

As the authorizing physician, I will review, on a biennial basis, the activities of the health care providers administering the vaccine under this protocol.

Date: _____
*MUST BE RENEWED WITH PHYSICIAN ON A BIENNIAL BASIS

Physician Signature: _____

Physician Name: _____

Address:_____

City: _____State:____ Zip:_____

Medical License #: _____

Pharmacist in Charge Name: _____

Pharmacist in Charge Signature:_____

Date _____ Pharmacist in Charge License #_____

Pharmacy Name:_____

Pharmacy Address: _____

City: _____State:____ Zip:_____

PHYSICIAN/BOARD OF HEALTH NOTIFICATION
Notify the individual's primary care physician, or if the individual has no family physician, the County Board of Health of the district in which the individual lives, within 30 days after administering the immunization; document accordingly.

