

June 25, 2018

New Herpes Zoster Vaccine Shingrix® Expected to Become Available for Vaccines for Adults (VFA) Sites in July 2018

Vaccine pre-release guidance for VFA program enrolled sites

Background

On October 20, 2017, the United States (U.S.) Food and Drug Administration (FDA) licensed Shingrix®, a 2-dose recombinant, adjuvanted vaccine for use in adults ages 50 years and older for the prevention of herpes zoster. On October 25, 2017, the Advisory Committee on Immunization Practices (ACIP) recommended the recombinant zoster vaccine (RZV) for use in immunocompetent adults ages 50 years and older. The ACIP made a preferential recommendation for RZV over the existing Zoster Vaccine Live (ZVL, Zostavax®) for the prevention of herpes zoster and related complications.

This communication is meant to provide you with practical guidance to best prepare your practice for a successful transition from the existing Zoster Vaccine Live (ZVL, Zostavax®) to the new shingles vaccine, Shingrix®, in anticipation of the new vaccine becoming available through the Vaccines for Adults (VFA) Program in July 2018. Additional information on vaccine dosage, administration, and recommendations will be included in the program communication, to be sent once the vaccine becomes available for ordering.

Zoster Vaccine Availability through VFA

The California Department of Public Health, Immunization Branch is following ACIP's recommendations for the preferential use of the new recombinant Zoster vaccine, Shingrix®. Shingrix® will replace Zostavax® in the list of vaccines provided through the Vaccines for Adults (VFA) Program.

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Zostavax® will remain available to VFA providers for a limited time (anticipated through the end of September 2018), allowing VFA providers to develop and implement a transition plan, ensure all staff administering and managing vaccines are familiar with the new product, and reduce/deplete existing inventories of Zostavax®.

Table 1 provides a succinct comparison of the main features of Zostavax®, the existing shingles vaccine, and Shingrix®, the new vaccine.

Ordering Guidelines

Shingrix® is anticipated to become available for ordering through the MYVFCVaccines ordering system in July 2018. In an effort to reduce provider inventories of Zostavax® prior to the introduction of Shingrix®, the VFA program began limiting Zostavax® orders starting in the second quarter (Q2) of 2018 ordering period.

Table 1. Comparison of the main features of Shingrix® and Zostavax® vaccines

	Shingrix® (RZV)	Zostavax® (ZVL)
Storage	Refrigerator (between 36°F and 46°F) - Store both vials together in refrigerator before reconstitution. DO NOT FREEZE.	Freezer (between -58°F and +5°F) for powder containing vial. Diluent should be stored at room temperature or refrigerator.
Vaccine Type	Recombinant, adjuvanted (non-live)	Live
Route of Administration	Intramuscular (IM) – 0.5ml / dose	Subcutaneous (SQ) – 0.65ml / dose
Dose Interval	2 dose series, spaced 2 to 6 months apart*	Single dose
Recommended Age	≥ 50 years**	≥ 60 years (FDA licensure is ≥ 50 years)

*Minimum interval for Shingrix® immunization after Zostavax® is 8 weeks.

**Even people who have had shingles or previously got Zostavax® are recommended to be vaccinated with Shingrix®.

Providers with Zostavax® doses on hand should do their best to administer remaining doses to patients, prior to the transition to the new product. However, if the clinic still

has a few doses of Zostavax® in the inventory despite the efforts to vaccinate eligible patients by the time Shingrix® becomes available, the clinic should complete a Vaccine Return Form.

In order to prepare for placing your first vaccine request for this new product, please make sure your clinic takes into consideration:

- **Recommended age for Shingrix®:** The age recommendation for Shingrix® is lower than the recommended age for Zostavax®; Shingrix® is recommended for persons 50 years of age and older.
- **Number of VFA Zostavax® doses administered during each of the previous quarters.** This will not only guide your target order for your next quarterly order, but it will also give you an indication of the number of patients your clinic may contact to notify about the new product, and encourage them to schedule an appointment to receive Shingrix®.
- **VFA Eligibility:** Of the total number of patients for whom the new vaccine is recommended, consider only those who meet VFA eligibility.

Eligible Persons for Receipt of VFA Supplied Shingrix®

Adults 19 years of age and older may receive SHINGRIX® provided by the VFA program if they are:

- Uninsured – no public or private health insurance coverage, OR
- Underinsured – health insurance does not cover Shingrix®. If the patient's health insurance covers Zostavax®, but does not cover Shingrix®, the patient is considered underinsured for the purpose of the VFA program.

Note: For Medicare patients, Shingrix® is a covered pharmacy benefit under Medicare Part D. Therefore, patients who have Medicare Part D are NOT eligible to receive the VFA-supplied Shingrix® vaccine.

Make sure you have a plan in place to recall your patients for the second dose of the Shingrix® vaccine.

Provider Recommendation

Frame the recommendation for RZV vaccination as the best way to protect against shingles and associated complications. **Make sure you follow the elements of the standards for adult immunization practice (Assess, Recommend, Administer or Refer, and Document) to immunize all your adult patients who are overdue for vaccines.**

Storage guidelines

Unlike Zostavax®, which is a frozen vaccine, **Shingrix® is a vaccine that should be**

refrigerated between 2° and 8°C (36° and 46°F). This vaccine cannot freeze, and it must be protected from light.

Make sure appropriate space is made available in your refrigerator, and is labeled appropriately as you prepare to receive and store doses when it becomes available for ordering.

TRAINING AND SYSTEMS

Staff Training

Ensure that all your staff who is involved in adult vaccine management and vaccine administration, and particularly any staff in charge of receiving and storing vaccine is aware of the upcoming transition to a new shingles vaccine and has received training relevant to the new vaccine storage, administration, coding, age-related recommendation information, etc.

System Readiness

Make sure that the forecasting and clinical decision support tools (health maintenance forms/best practice alerts) are active/turned on in your EHR, and the information is updated for the new ACIP preferential Shingrix® recommendation: 50 years and older for the new vaccine, Shingrix® vs. 60 years and older for Zostavax®.

Make sure the appropriate eligibility categories are set-up in your clinic's EMR/EHR for appropriate documentation of VFA eligibility for the new vaccine.

Work with your billing department to ensure a vaccine administration fee is NOT billed for any VFA vaccine, including Shingrix®.

Strategies for Successful Vaccine Uptake

Use one of the **strategies** outlined below to improve the uptake of the new vaccine that is highly effective in protecting your patients from shingles and postherpetic neuralgia.

Routine visit strategy:

- Focus on ANY patients coming in to the clinic for other reasons
 - a. During pre-visit planning, use your EHR or registry to identify any patient needing that vaccine. For Zoster, this would be patients 50 years and older who have no record of receiving a Zoster vaccine.
 - b. Set up a workflow depending on the patient's insurance status
- Uninsured patients: immunize on site using VFA vaccine.

- Medi-Cal patients: immunize on site using health center-purchased vaccine, or refer to the patient's network pharmacy. All routinely recommended adult immunizations, including Zoster vaccine, are included as a pharmacy benefit, whether the patient is in a managed care plan or the Fee for Service program.

Recall strategy: Reach out to VFA eligible patients 50 years and older to ask them to come to the clinic to receive the new Zoster vaccine.

- Run a report from your practice electronic health record (EHR)/population health management system (i2i, DRVS, etc.) or immunization registry of active, uninsured, patients 50 years and older who have no record of receiving the Zoster vaccine, or who have received Zostavax® 2 months or longer ago.
- Decide whether to schedule routine appointments for vaccine administration, or hold a vaccination clinic for those patients.
- Recall patients using your clinic's reminder/recall systems (staff phone calls, text messaging, mailed reminder cards).

You may also want to run a report of all active, uninsured, patients 65 years and older who have no record of receiving PCV13 vaccine. You can do this as a stepwise strategy: Recall all active, uninsured, patients 65 years and older who are overdue for EITHER the PCV13 vaccine and/or the Zoster vaccine, and then move on to the 50-65 year old active, uninsured, patients who are overdue for Zoster. Patients identified as overdue for PCV13 AND RZV vaccine can receive both vaccines during the same visit.

QUESTIONS

If you have any questions, please contact my317vaccines@cdph.ca.gov.

Attachment: IMM-1212, Vaccine Fact Sheet: Zoster/Shingles (HZV)