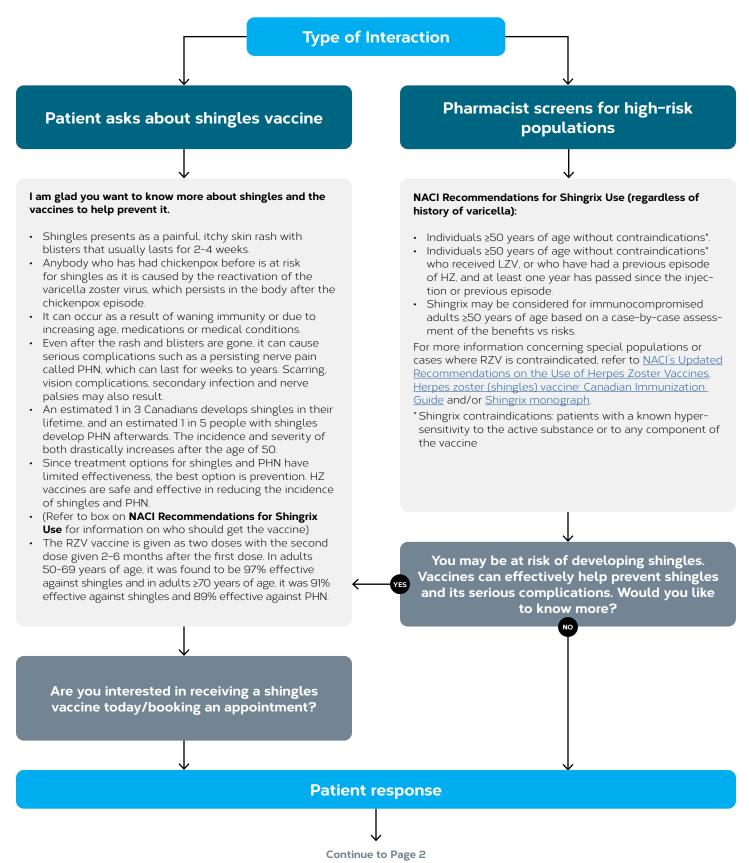
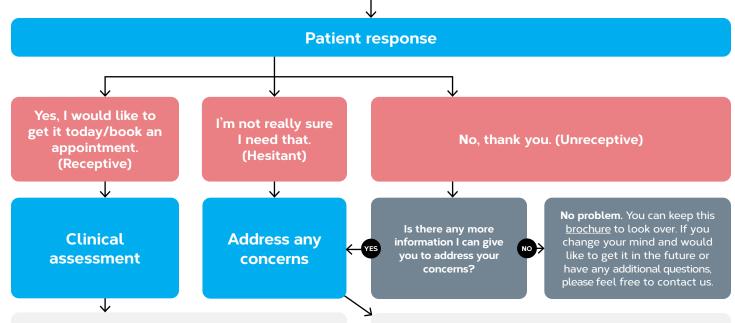
Pharmacist Clinical Tool for Initiating Shingrix Discussions

Shingrix is the first non-live adjuvanted recombinant zoster vaccine (RZV) to help protect adults 50 years of age or older against shingles.







Key Considerations

Review the patient's medical history to determine if vaccination with Shingrix would be appropriate, e.g.:

- Is the vaccine indicated? (Refer to the box on NACI Recommendations for Shingrix Use)
- Does the patient have any contraindications to the vaccine?
- Are there any warning signs or precautions to take into consideration?
 - Illness: Postpone in those with severe acute illness with or without fever. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination
 - Hematologic: Use with caution in those with thrombocytopenia or any coagulation disorder.
 - Syncope: Procedures should be in place to prevent injuries from fainting as it may occur following or before any vaccination.
 - Special Populations: No data on the use of Shingrix in pregnant or nursing women. Safety and efficacy in individuals <18 years of age has not been established. Limited data on the use in immunocompromised adults 50 years of age or older; RZV may be considered on a case-by-case assessment of benefits vs risks and should be administered at least 14 days prior to the initiation of immunosuppressive drugs.
- What is the patient's vaccination history and past vaccination experiences (e.g., undesirable events)?
- Can Shingrix be administered simultaneously with other vaccines?
 - According to the Canadian Immunization Guide, in general, Shingrix can be given given concomitantly with, before or after, other inactivated or live vaccines for different diseases. For concomitant parenteral vaccines, administration should be at different injection sites using separate needles and syringes.
 - Fever and shivering were more frequent when the pneumococcal 23-valent polysaccharide vaccine (Pneu-P-23) was co-administered with Shingrix.

Frequently Asked Questions

Q: How does Shingrix work?

A: Shingrix is a non-live vaccine that contains an antigen that triggers a targeted immune response in the body to the vaccine, which helps the body build its own protection against shingles. It is also combined with an adjuvant to improve the body's response to the vaccine. See here for a video on how the vaccine works in your body.

Q: Is Shingrix effective?

- $\ensuremath{\mathbf{A}}\xspace$ In clinical studies, two doses of Shingrix were demonstrated to be:
 - 97% effective in preventing shingles in individuals 50-69 years of age; 91% effective in individuals ≥70 years of age
 - 91% effective in preventing PHN in individuals ≥50 years of age overall; 89% effective in those ≥70 years of age

Shingrix maintained efficacy for four years in studies, but the exact duration of protection beyond the initial four years is currently under investigation.

Q: Is Shingrix safe?

A: Yes. Vaccines are tested and licensed in Canada before they are given to the public. Additionally, information about side effects is continuously collected to monitor safety. (See the Sample Counselling Script for a list of common side effects.)

Q: Can Shingrix cause shingles?

A: No. Shingrix is a non-live vaccine, which means it does not contain any live components of the virus, so it can not cause shingles.

Q: If I've already had shingles, do I still need to be vaccinated?

A: Yes. It is still recommended that individuals who have had shingles be vaccinated. Most people will have only one occurrence of shingles in their lifetime; however, shingles is a reactivation of the chickenpox virus, which may occur more than once.

Q: Is Shingrix the only vaccine available for shingles prevention?

A: There are two HZ vaccines available in Canada: Shingrix (a non-live recombinant zoster vaccine) and Zostavax II (a live zoster vaccine). According to NACI, although both vaccines are safe and effective, vaccine efficacy against HZ decreases with age and over time after vaccination. However, vaccine efficacy of RZV appears to decline more slowly than vaccine efficacy of LZV across all age groups. Therefore, NACI recommends Shingrix be offered to most individuals ≥50 years of age unless contraindicated.

Triage

Continue to Page 3

Triage

Discuss Vaccine/Administration Costs

· Eligibility for publicly funded programs:

- OHIP: Ontario seniors between the ages of 65 to 70 are eligible to receive Shingrix through the publicly funded program from their primary health care provider, provided they have not already received the Zostavax II vaccine through the Ontario publicly funded shingles immunization program.
- <u>VAC</u>: Standard benefit for eligible members 50 years of age or older with a prescription from a health professional authorized to prescribe pharmaceuticals.
- NIHB: Listed on the NIHB Drug Benefit List as a limited use product (no prior approval required) for eligible individuals between the ages of 65 and 70. Prior approval is required for immunocompromised patients on an exceptional basis. Pharmacy providers can also be reimbursed up to \$18 for the administration of Shingrix if certain conditions are met.
- **Private third-party coverage**: Depends on the patient's private insurance plan; some may cover all or part of the cost of Shingrix. Patients should contact their private insurer for more information on coverage.
- Out of pocket expenses: Provide patient with the cost of Shingrix.
- Pharmacy vaccine administration fee: Provide patient with the pharmacy's vaccine administration fee; OPA members can also refer to OPA's Suggested Fee Guide for more information

Administration Book an appointment Refer to primary care provider OR defer service to a later time

Key Considerations

Reconstitution

Shingrix is available as a 0.5 mL suspension for one injection made by combining:

- · One vial of gE powder
- One vial of adjuvant suspension

Shingrix must be reconstituted prior to administration using the accompanying adjuvant suspension.

- 1. Visually inspect the lyophilized powder and suspension for any foreign particulate matter and/or variation of appearance. Do not reconstitute the vaccine if either is observed.
- 2. Withdraw the entire content of the vial containing the suspension into a sterile syringe.
- 3. Add the entire contents of the syringe into the vial containing the lyophilized powder.
- 4. Shake gently until the lyophilized powder is completely dissolved. It should be an opalescent, colourless to pale brownish liquid.
- 5. Visually inspect the reconstituted vaccine for any foreign particulate matter and/or variation of appearance. Do not administer the vaccine if either is observed.
- 6. Withdraw the entire contents of the vial containing the reconstituted vaccine into a sterile syringe.
- 7. Change the needle so that a new needle is being used to administer the vaccine.

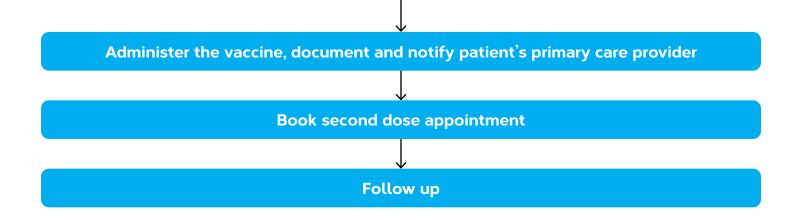
Note: After reconstitution, the vaccine should be used promptly; if this is not possible, the vaccine should be stored in a refrigerator (2°C to 8°C). If not used within 6 hours, it should be discarded.

Administration

• Shingrix should be administered intramuscularly, preferably in the deltoid muscle using proper aseptic technique. Do NOT administer the vaccine intravascularly, intradermally, or subcutaneously.

Sample Counselling Script:

- Shingrix is a non-live vaccine that provides protection against shingles. It is given in 2 doses with the second dose given 2-6 months after the first dose. It is important to get both doses to make sure you have maximum protection against shingles.
- In clinical studies, Shingrix was shown to be more than 90% effective in preventing shingles in people over the age of 50 years old. It is known to provide good protection for 4 years and researchers are currently studying how well Shingrix works after the initial 4 years post-vaccination. (Note: as with all vaccines, not all individuals who are vaccinated will mount a protective immune response.)
- Like all vaccines, Shingrix can cause side effects. Not everyone will experience side effects and even if they do, most are usually mild to moderate and last only 2-3 days. Some common side effects include:
 - · redness, pain, swelling, itching where the needle was given
 - · fever, chills, headache
 - feeling tired or unwell, muscle aches
 - nausea, vomiting, diarrhea or stomach pain
 - There are some rare side effects, such as allergic reactions including rash, hives, swelling of the face, tongue, or throat which may cause difficulty in swallowing or breathing.
 - If any of these side effects gets serious, contact your healthcare professional immediately. These are not all the possible side effects and if you experience any other side effects that are concerning, please contact your healthcare professional.
- For your safety, please stay in the pharmacy for 15 minutes after immunization for monitoring in case you have any rare but serious reactions.



Abbreviations

HZ: herpes zoster; LZV: live zoster vaccine; NACI: National Advisory Committee on Immunization; NIHB: Non-Insured Health Benefits Program; OHIP: Ontario Health Insurance Plan; PHN: postherpetic neuralgia; RZV: recombinant zoster vaccine VAC: Veteran Affairs Canada

DISCLAIMER:

This tool was developed by the Ontario Pharmacists Association (OPA) with a grant provided by GlaxoSmithKline Canada (GSK). The information provided in this document is intended to assist pharmacists with initiating discussions with patients about RZV but does not replace professional judgement and responsibilities. It is intended to supplement materials provided by regulatory authorities, and should there be any discrepancies, municipal, provincial, and federal laws, policies and guidelines shall prevail. The information provided in this document are current at the time of publication. The decision for use and application of this document is the responsibility of the user. OPA assumes no liability for such use and application or any resulting outcomes.

REFERENCES:

Canadian Immunization Guide. Herpes zoster (shingles) vaccine. Last updated Feb. 13, 2020. Accessed Sept. 6, 2021. <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-8-herpes-zoster-(shingles)-vaccine.html

Evans, GA. Herpesvirus Infections. Therapeutic Choices: Canadian Pharmacists Association. Last updated Apr. 14, 2021. Accessed Sept. 6, 2021. http://www.myrxtx.ca

GlaxoSmithKline. Shingrix: The First Non-live Adjuvanted Vaccine to Help Protect Against Shingles. Accessed Sept. 7, 2021. https://ca.gsk.com/media/1598992/13419_gsh_dtc_factsheet_en_05_clean_final_2019.pdf

GlaxoSmithKline. Shingrix Product Monograph. Last updated June 3. 2020. Accessed Sept. 7, 2021. https://cagsk.com/media/1350788/shingrix_pm-2017-10-13.pdf

National Advisory Committee on Immunization. Updated Recommendations on the Use of Herpes Zoster Vaccines. Last updated Aug. 30, 2018. Accessed Sept. 7, 2021. https://www.canada.ca/en/services/health/publications/healthy-living/updated-recommendations-use-herpes-zoster-vaccines.html

GlaxoSmithKline. Shingrix Efficacy Data. Accessed Sept. 7, 2021. https://shingrixhcp.com/efficacy-safety/efficacy-data/

GlaxoSmithKline. Shingrix Patient Brochure. Last updated Sept. 2018. Accessed Sept. 7, 2021. https://gskpro.com/content/dam/global/hcpportal/en_CA/products/Shingrix/pdfs/SHIN-GRIX%20Patient%20Brochure.pdf

Ontario Ministry of Health. Ontario Publicly Funded Shingles (Herpes Zoster) Immunization Program: Shingrix® Vaccine Information for Patients. Accessed Sept. 7, 2021. https://www.health.gov.on.ca/en/public/programs/immunization/docs/shingles-patient_fact_sheet_en.pdf

Date created: September 17, 2021