Indian Health Service
Division of Epidemiology and Disease Prevention
National Immunization Program

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Recombinant Zoster Vaccine (RZV) – *Shingrix*

Vaccine Recommendation Update

SUMMARY OF RECOMMENDATIONS

On October 20, 2021, the Advisory Committee on Immunization Practices (ACIP) expanded recommendations for use of recombinant Zoster vaccine (Shingrix) to immunocompromised adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy.[1] Shingrix is the first herpes zoster (HZ) vaccine approved for use in immunocompromised persons.

RECOMMENDATIONS FOR VACCINE USE

Vaccine Information Statement (VIS)

ACIP Recommendations & Eligible Groups for Receipt of Zoster[1]

The Shingrix vaccine has been approved for use and endorsed by the ACIP for the prevention of HZ in all individuals 50 years and older since 2018. With the expanded ACIP recommendations, Shingrix is now also indicated for the prevention of HZ and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy. This recommendation addresses disproportionately affected individuals, as the risk for HZ among younger adults with certain immunocompromising conditions can be comparable to or higher than that in the general adult population aged >50 years.

Dosing, Timing & Administration[2]

Shingrix is administered intramuscularly as a 2-dose series, regardless of previous history of HZ or previous receipt of the previously available live zoster vaccine.

- The second dose should be given 2-6 months after the first dose. This can be reduced to 1-2 months for people who have or will have a weakened immune system.
- When possible, patients should be vaccinated before becoming immunosuppressed. Otherwise, providers should consider timing vaccination when the immune response is likely to be most robust (e.g., during periods of lower immunosuppression and stable disease or planned drug holidays).
- If the second Shingrix dose is given sooner than 4 weeks after the first, a valid second dose should be repeated at least 4 weeks after the early dose.
- Do not restart the series if more than 6 months have elapsed since the first dose.

Efficacy and Cost-Effectiveness[1]

Vaccination in this group is cost-saving, with a number needed to treat of 8-10 to prevent one episode of HZ, using hematopoietic cell transplant patients as the base case.[3] Also, a significant reduction in post-herpetic neuralgia and hospitalization were demonstrated in clinical trials for vaccinated individuals.[4]

- Estimates of vaccine efficacy (VE) in immunocompromised individuals in the published ACIP recommendations came from three studies:
  - VE of 68.2% (95% CI = 55.6%–77.5%) for autologous hematopoietic cell transplant recipients.[4]
  - VE of 87.2% (95% CI = 44.3%–98.6%) in post hoc efficacy analyses for patients with hematologic malignancies.[5]
  - VE of 90.5% (95% CI = 73.5%–97.5%) in post hoc efficacy analyses for patients with potential immune-mediated diseases (solid organ transplant recipients, patients living with HIV, patients with breast cancer, and patients with autoimmune and inflammatory conditions).[6]

Administration[7]

Shingrix is a 2-dose vaccine administered as a 0.5mL intramuscular injection and is supplied in two vials that must be combined prior to administration. It is a subunit vaccine containing recombinant glycoprotein E in combination with an adjuvant ($AS01_B$). Shingrix can be administered concomitantly, at different anatomic sites, with other adult vaccines including COVID-19 vaccines. Coadministration of Shingrix with adjuvanted influenza vaccine (e.g., Fluad) and COVID-19 vaccines is being studied.

Contraindications[1,7]

Shingrix should not be administered to persons with a history of a severe allergic reaction, such as anaphylaxis, to any component of this vaccine, or to individuals with a previous allergic reaction to a dose of Shingrix.

Precautions[1,7]

- Vaccination should be delayed for patients experiencing moderate or severe acute illness.
- If a person is experiencing an episode of HZ, vaccination should be delayed until the acute stage of the illness is over and symptoms abate.
- Additional precautions can be found in the Shingrix Prescribing Information, including risk of Guillain Barre Syndrome.[2]
- There is no ACIP recommendation for Shingrix use in pregnancy, consider delaying vaccination until after pregnancy.

STORAGE AND HANDLING

Shingrix should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze.

AVAILABILITY, ORDERING, AND SUPPLY

All ACIP recommended vaccines are on the National Core Formulary.[8] Shingrix is manufactured by GlaxoSmithKline. Shingrix is available under the Veterans Administration pricing contract under the IHS Prime Vendor, McKesson.[9]

ADVERSE REACTIONS AND REPORTING

Post-vaccination adverse reactions that are mild to moderate in nature are common with Shingrix. Injection site reactions, such as pain, redness, or swelling at the site of the injection are common. Systemic adverse reactions, such as myalgias, shivering, fatigue, fever, and stomach upset may occur and may last 2-3 days. Before vaccination, providers should counsel patients about expected local or systemic reactogenicity, including reactions that may limit normal daily activities.

Adverse events following vaccination should be reported according to local policy and to the Vaccine Adverse Events Reporting System (VAERS). For VAERS reporting within the IHS, including Tribal and Urban facilities, healthcare providers are requested to add “IHS” in item #26 for ongoing vaccine safety evaluation among the IHS patient population.[10]

RPMS-EHR DOCUMENTATION AND FORECASTING

IHS EHR Forecaster logic is currently age-based and already exists for adults aged 50 and older.

- First and second doses are forecasted based on a 2-dose series, with a minimum forecasted interval of 2 months.
- Additional forecaster logic may be found here: Zoster Vaccine Group – ICE

The forecaster will not forecast for first or second doses for immunocompromised individuals aged 19-49 years.

- Additional information: CVX code 187; CPT code 90750; CPT name HZV Vaccine Recombinant IM
- CPT Description: Zoster (Shingles) Vaccine (HZV), Recombinant, Subunit, Adjuvanted, For Intramuscular use.

If there are any questions regarding this document, please email the National Immunization Program at ImmunizationAdmins@ihs.gov.

REFERENCES AND APPENDIX

1. Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov)
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