



Pharmacy Preferred Newsletter January 2021

Shingrix Vaccine

Background: Herpes zoster, colloquially referred to as “Shingles” is a painful skin rash that is caused by a prior infection of the same virus that is known to cause Chicken Pox, varicella zoster. The varicella zoster virus remains dormant after infection but can be reactivated especially in older adults who have weaker immune systems. The rash typically presents with erythema and blistering that wraps around the left or right torso. Triggers of Herpes zoster include but are not limited to: use of immunosuppressants, emotional stress, exposure to virus, and presence of malignancy. Historically, there were two vaccines that can help prevent Shingles, Shingrix and Zostavax. Shingrix is the newer and preferred vaccine due to it being superior to Zostavax in preventing Shingles and complications associated with it such as postherpetic neuralgia. Shingrix vaccine is inactivated (not live), meaning it uses a dead version of the virus, eliminating the risk of transmission

Why Get Vaccinated?

- Roughly 1 in 3 individuals will get shingles in their lifetime
- Risk of getting shingles and serious complications goes up as you get older
- Roughly 1 in 10 individuals who get shingles will develop postherpetic neuralgia, which can cause long term nerve pain that can last for months to years.
- Shingles can cause blindness in rare instances

Who Should Not Get the Vaccine?

- Have had an allergic reaction to any component of vaccine
- Currently have a temperature greater than 101.3 degrees
- Currently pregnant
- Patients with an acute episode of Herpes zoster
- Serologic evidence of susceptibility to varicella

Administration

- Shingrix is a two-dose series to be given two to six months apart
- Shingrix should be injected intramuscularly
- If more than six months have passed, a second dose should be administered as soon as possible
- Shingrix Vaccine needs to be reconstituted and stored in a refrigerator if not administered immediately

Patients with Past History of Zostavax Vaccine

As of November 18, 2020, Zostavax is no longer available in the United States. There are no theoretical or data concerns to indicate that Shingrix would be less safe or effective if administered less than five years after a patient received Zostavax. Studies have shown waning effectiveness of Zostavax as time passes, leaving recipients with reduced protection against Herpes zoster. You should wait at least **8 weeks** after a patient received Zostavax to administer Shingrix.

Note: history of chicken pox and testing for antibodies is not required. If someone is incidentally found not to have varicella antibodies, they should receive the varicella vaccine first.

References

1. Food and Drug Administration. Shingrix [package insert]. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2017. <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM581605.pdf>
2. CDC. Update on herpes zoster vaccine: licensure for persons aged 50 through 59 years. MMWR Morb Mortal Wkly Rep 2011;60:1528. 8. Hales CM, Harpaz R, Ortega-Sanchez I, Bialek SR. Update on recommendations for use of herpes zoster vaccine. MMWR Morb Mortal Wkly Rep 2014;63:729–31.
3. Insinga RP, Itzler RF, Pellissier JM, Saddier P, Nikas AA. The incidence of herpes zoster in a United States administrative database. J Gen Intern Med 2005;20:748–53. <https://doi.org/10.1111/j.1525-1497.2005.0150.x>

COVID-19 Vaccine Updates

(As of December 2020)

Moderna Vaccine (mRNA 1273)

Interim results: Vaccine is shown to be 94.1% efficacious at prevention of symptomatic COVID-19 infection, measured starting 7 days after second dose

- Currently in Phase 3 in clinical trials
- Primary Endpoint: Prevention of symptomatic COVID-19
- Estimated Enrollment: 30,000
- Experimental arm: Patients received 100 ug IM injection of mRNA-1273 on day 1 and day 29
- Placebo arm: 0.9% sodium chloride (normal saline) injection
- EUA has been approved by FDA on December 18, 2020

Storage: remains stable at 2° to 8°C (36° to 46°F), the temperature of a standard home or medical refrigerator, for 30 days Remains stable at -20° C (-4°F) for up to six months

Handling: No dilution required at vaccination site
Safety: Interim data was considered safe after review by an independent data and safety monitoring board

Pfizer/BioNTech Vaccine

Interim results: 95% effective at prevention of COVID-19 symptomatic infection beginning 14 days after the second dose.

- Currently in Phase 3 in clinical trials
- Estimated enrollment: 45,000
- Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose
- EUA has been approved by FDA on December 11, 2020
- 170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group

Storage: remains stable at 2° to 8°C (36° to 46°F), the temperature of a standard home or medical refrigerator, for 5 days

Handling: Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

Safety: Interim data was considered safe after review by an independent data and safety monitoring board

Statin Use in Persons with Diabetes

Patients with diabetes are at high risk for developing cardiovascular disease. ADA guidelines recommend the use of statins for primary and secondary prevention of ASCVD events.

ADA Recommendations

For patients with diabetes aged 40–75 years without atherosclerotic cardiovascular disease, use moderate-intensity statin therapy in addition to lifestyle therapy for primary prevention

For patients of all ages with diabetes and atherosclerotic cardiovascular disease, high-intensity statin therapy should be added to lifestyle therapy for secondary prevention

In patients with diabetes at higher risk, especially those with multiple atherosclerotic cardiovascular disease risk factors or aged 50–70 years, it is reasonable to use high-intensity statin therapy.

Definition of SUPD (Statin Use in Persons with Diabetes)

measure: The SUPD measure is a PQA (pharmacy quality alliance) measure based off ACA/AHA guidelines of patients ages 40–75 who were dispensed at least two diabetes medication fills and who received a statin medication fill during the measurement period. This measure does not allow for exclusions for myalgia, myositis, and rhabdomyolysis.

Coding and Documentation: Statin use is determined through medication claims data, and no physician coding is required. *However, it is important to document discussions with patients regarding the need for statins.* In addition, documentation regarding compliance or non-compliance with prescribed treatment should be done at the time of the office visit and also when medication reconciliation is performed.

Note: There are two related measures:

Medication Adherence for Cholesterol (statins)

- ❖ This Star measure has a weighting of three. The denominator includes members age 18 or older who have two fills for a statin. The numerator is met if the Proportion of Days Covered (PDC) is 80% or higher.

Statin Therapy for Patients with Cardiovascular Disease (SPC)

- ❖ This Star measure is similar to diabetes, but SPC requires the statin be a moderate-to-high intensity statin. If a patient qualifies for both measures (cardiovascular disease and diabetes), they should meet the requirements of both measures by receiving a moderate-to-high intensity statin.

Making Connections

We welcome your feedback and future topic ideas.

Email us at: PharmacyR@chpw.org