

Medical Policy Reference Manual

Medical Policy

5.01.016 Zoster Vaccine, (GlaxoSmithKline) Shingrix®

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Description

Herpes zoster (HZ) is commonly known as shingles or zoster and is a manifestation of the reactivation of the varicella zoster virus (VZV). VZV, as a primary infection, produces chicken pox (varicella). Following chicken pox, the virus lies dormant in the ganglia adjacent to the spinal cord (called the dorsal root ganglion) or in the cranial base. If it reactivates as shingles, it affects only a single nerve fiber or ganglion, which can radiate to only one side of the body. Generally, one's immune system prevents or suppresses reactivation of the virus; however, in the elderly, or those with a suppressed immune system, protection is compromised.

Shingrix® (recombinant zoster vaccine, or RZV) , a non-live vaccine, is indicated for the prevention of herpes zoster (shingles) in adults aged 50 years and older and for immunodeficient or immunosuppressed adults aged ≥19 years. Shingrix® is not indicated for the prevention of primary varicella infection (chickenpox). Shingrix® is administered in 2 doses given by intramuscular injection, the initial followed by a second dose at 2 to 6 months.

Zostavax®, a live attenuated virus vaccine, is not a treatment for shingles or postherpetic neuralgia. Zostavax® is given as a single dose by subcutaneous injection. **As of July 1, 2020, Oka/Merck ceased production of Zostavax®. Per the Centers for Disease Control and Prevention (CDC), Zostavax® is no longer available for use within the United States as of November 18, 2020.**

Policy

Shingrix® (GlaxoSmithKline) is considered a medically necessary preventive service in individuals fifty (50) years of age and older for the prevention of herpes zoster (shingles).

Shingrix® (GlaxoSmithKline) is considered medically necessary for the prevention of herpes zoster and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy.

A prescription *may* be required.

Policy Guidelines

Rationale:

Update 2022:

A search of the peer-reviewed literature was performed for the period of February 2021 through April 2022. Findings in the recent literature include updated guidelines from the ACIP expanding the medically necessary indications for immunodeficient or immunosuppressed adults aged ≥19 years. Therefore, the policy statement has been changed to include updated medically necessary indications for Shingrix® (GlaxoSmithKline).

Update 2021:

A search of the peer-reviewed literature was performed for the period of January 2019 through February 2021. Findings in the recent literature do not change the conclusions on the Zoster vaccine conditions other than the medically necessary indications listed within the Policy section of this document. Therefore, the policy statement is unchanged.

Benefit Applications

Coverage of preventive health care services, including immunizations, is defined by contract. Therefore, the member's contract should be consulted to be certain of limitations of coverage prior to quoting benefits, adjudicating claims, or performing services.

Benefits **are not provided** for preventive services when the member does not have coverage for preventive services under their contract.

Benefits **are provided** for preventive services when:

- the member has coverage for preventive services under their contract; and
- the services rendered meet the criteria for coverage (if any), as specified in the member's contract.

NOTE: For FEP business check the member's contract for benefits.

Provider Guidelines

On October 2006, the ACIP provided provisional recommendations to the Center for Disease Control (CDC) for review. These recommendations will not become official until published in the CDC's Morbidity and Mortality Weekly Report (MMWR) anticipated in June 2007.

May 15, 2008, the CDC released in the MMWR the Recommendations of the Advisory Committee on Immunization Practices (ACIP) on Prevention of Herpes Zoster,

On March 24, 2011, the U.S. Food and Drug Administration (FDA) approved an expanded age indication for Zostavax® for the prevention of herpes zoster in adults 50 years of age and older.

On October 20, 2017, the U.S. FDA approved Shingrix® for adults aged 50 years and older to prevent shingles.

On October 25, 2017, the Advisory Committee on Immunization Practices (ACIP) voted that Shingrix® is:

- recommended for healthy adults aged 50 years and older to prevent shingles and related complications
- recommended for adults who previously received the current shingles vaccine (Zostavax®<https://www.cdc.gov/Other/disclaimer.html>) to prevent shingles and related complications
- the preferred vaccine for preventing shingles and related complications

These recommendations will not become official until published in the *Morbidity and Mortality Weekly Report*. At that time, the recommendations will become official policy.

On February 9, 2018, the CDC released in the MMWR the updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) on Prevention of Herpes Zoster:

- Administer 2 doses of recombinant zoster vaccine (RZV) (Shingrix) 2–6 months apart to adults aged 50 years or older regardless of past episode of herpes zoster or receipt of zoster vaccine live (ZVL) (Zostavax).
- Administer 2 doses of RZV 2–6 months apart to adults who previously received ZVL at least 2 months after ZVL.
- For adults aged 60 years or older, administer either RZV or ZVL (RZV is preferred).

On November 18, 2020, Zostervax® by Oka/Merck is no longer available for use in the United States as reported by the CDC.

On October 20, 2021, the Advisory Committee on Immunization Practices recommended 2 RZV doses for prevention of herpes zoster and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy.

Cross References to Related Policies and Procedures

10.01.003A Preventive Services, Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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This policy statement relates only to the services or supplies described herein. Coverage will vary from contract to contract and by line of business and should be verified before applying the terms of the policy.