



Clinical Edit Criteria Proposal

Drug/Drug Class: Zostavax[®] (Zoster Vaccine Live) Injection / Herpes Zoster Vaccine
 Date: June 27, 2012
 Prepared for:
 Prepared by: MO HealthNet

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Zostavax[®] (zoster vaccine live).

Why was this Issue Selected:

Zostavax[®] is an attenuated preparation of the strain of live varicella-zoster virus (VSV). It is an agent for active immunization that induces the endogenous production of antibodies, which protects against zoster and its complications. Zostavax[®] demonstrated efficacy for the prevention of herpes zoster (shingles) in individuals 50 years of age and older. It is at least 14 times more potent than the varicella virus vaccine that is currently approved for the prevention of varicella (chickenpox) in children. It is the first and only medical option approved for the prevention of shingles. Shingles is a blistering rash that is caused by the reactivation of the chickenpox virus, and can lead to serious complications including postherpetic neuralgia. The incidence, severity and frequency of shingles increases with age. Approximately 40-50% of the estimated 1 million cases of shingles that occur yearly in the U.S. develop in persons aged 50 and older.

Program-specific information:

Drug

- Zostavax[®]

Dose
 Single Dose Vial

Cost per Vial (WAC)
 \$177.65

Setting & Population:

Patients **50 years** of age and older

- Type of Criteria: Increased risk of ADE Non-Preferred Agent
 Appropriate Indications
- Data Sources: Only administrative databases Databases + Prescriber-supplied

Setting & Population

- Drug for review: Zostavax® (zoster vaccine live)
- Age range: Patients **50 years** of age and older
- Gender: Male and Female

Approval Criteria

- **Patients 50 years of age and older**
- Dosing limitation – single subcutaneous dose
- Administration outside of recommended age guidelines – subject to clinical consultant review

Denial Criteria

- Lack of approval criteria

References

1. Facts and Comparisons, p.1533ac – 1533ad; 2011.
2. USPDI, Micromedex, 2011.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2011.
4. Merck & Co., “Zostavax Product Submission/Package Insert”, Whitehouse Station, NJ, 08889; March 2011.