

MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

POLICY NUMBER: PAY.031.MH
REVISION DATE: 11/13
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SUBJECT: ZOSTAVAX Vaccine
INDEX TITLE: Medical Management
ORIGINAL DATE: November 2006

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL	CMS-MA
MedStar Select (X)	MedStar Medicare Choice (X)

I. POLICY

It is the policy of MedStar Health, Inc. to recognize the value of preventive medicine as appropriate and consistent with good medical practice and provide coverage of vaccines for prevention of Herpes Zoster and post herpetic neuralgia when the services are medically necessary (refer to CRM.015.MH Medical Necessity policy) as detailed in this policy and covered under the member's specific benefit plan.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the medically necessary indications for administering the ZOSTAVAX vaccine.

IV. SCOPE

This policy applies to various MedStar Health Departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

IV. PROCEDURE



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A. Background

Shingles, also known as herpes zoster or varicella zoster, is caused by reactivation of the dormant Varicella virus that causes chickenpox. Anyone who has been infected by chickenpox could develop shingles, though not all will. Increasing age and declining immunity are two major risk factors. Data indicate that 50% of those who live to age 85 will get the disease. As immunity weakens with advancing age, the virus can reactivate, multiply in, and damage sensory nerve cells to cause pain. It then migrates to the skin, causing the blistering rash of shingles.

Shingles may start with symptoms ranging from abnormal skin sensations such as itching or tingling, to severe pain on a single area of the body. Then, it may progress to a rash and fluid-filled painful blisters. It also can lead to post-herpetic neuralgia (PHN), a long-term nerve pain with its severity ranging from a tender, burning pain to a throbbing, stabbing pain, which can last for months or even years after the rash has healed.

ZOSTAVAX®, or the shingles vaccine, was developed specifically for and studied in older adults. Initial approval of the vaccine by the Food and Drug Administration (FDA) in 2006 was for use (single-dose) in people 60 years of age and older. Use of the vaccine was subsequently recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) in 2008. In 2011, the FDA approved the manufacturer's submission to support a label change for use of ZOSTAVAX to individuals 50-59 years of age. While ACIP has not yet altered its recommendation, the FDA currently approves the use of this vaccine in adults 50 years of age and older.

ZOSTAVAX is a lyophilized preparation of the live attenuated varicella-zoster virus (VZV). The risk of developing zoster in an individual is related to a decline in the VZV specific immunity. ZOSTAVAX® was shown to boost VZV specific immunity, and studies have indicated that the vaccine reduced the occurrence of shingles by approximately 51%, and reduced pain and discomfort by approximately 61% in those members between 60-80 years of age. The few studies in those over 80 years of age did not show such favorable outcomes.

B. Indications

This vaccine is covered **for adults 50 years of age or older.**

C. Limitations



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The following are contraindications for this vaccine:

1. HIV+ members with a CD4+ T lymphocyte count of <200 cells/ μ L
2. Members who take immunosuppressive doses of corticosteroids
3. Pregnancy or nursing mothers (Pregnancy should be avoided for 3 months post vaccination)
4. Active tuberculosis
5. History of allergic reaction (anaphylactic) to gelatin, neomycin or any other component of the vaccine
6. The vaccine should not be used in children
7. The vaccine should not be used for treatment of Zoster or PHN

Special Medicare Advantage clarification:

Zostavax® vaccine is covered only if the HMO or PPO benefit plan includes PART D prescription drug coverage.

If the Medicare Advantage benefit plan does **not** include prescription benefits, this vaccine is **not** a covered benefit.

D. Codes

The following code for treatment and procedure applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Code **Description**

90736 Zoster vaccine live for subcutaneous use.

E. Variations

N/A

F. Quality Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the MedStar Health's Technology Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

H. References

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10. Merck & Co., Inc. ZOSTAVAX® [Zoster Vaccine, Live, (Oka/Merck)]. Product Information, Accessed 10/28/2013.
<http://www.merckvaccines.com/Products/Zostavax/Pages/home>



11. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network (MLN) Matters No. SE0678.: Payment for Part D Vaccines under the Medicare Drug Benefit (Part D). . <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0678.pdf>
12. Schmader KE, Levin MJ, Gnann JW, et al. Efficacy, safety, and tolerability of Herpes Zoster vaccine in persons aged 50-59 years. Clin Infect Dis. 2012 Apr; 54(7), 922-928.
<http://cid.oxfordjournals.org/content/54/7/922.full.pdf+html>



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