



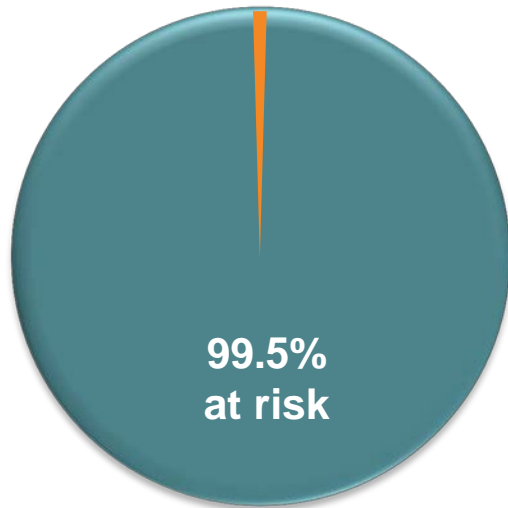
# Understanding the Risks and Consequences of Herpes Zoster

**ZOSTAVAX<sup>®</sup>**  
Zoster Vaccine Live

# Nearly all adults are at risk for herpes zoster<sup>1</sup>

- According to the Centers for Disease Control and Prevention (CDC):

**99.5%** of US adults aged  $\geq 40$  years are **at risk** for **herpes zoster** because they had chickenpox.<sup>1</sup>



Approximately **1 in 3** people will **experience herpes zoster** in their lifetime.<sup>1</sup>

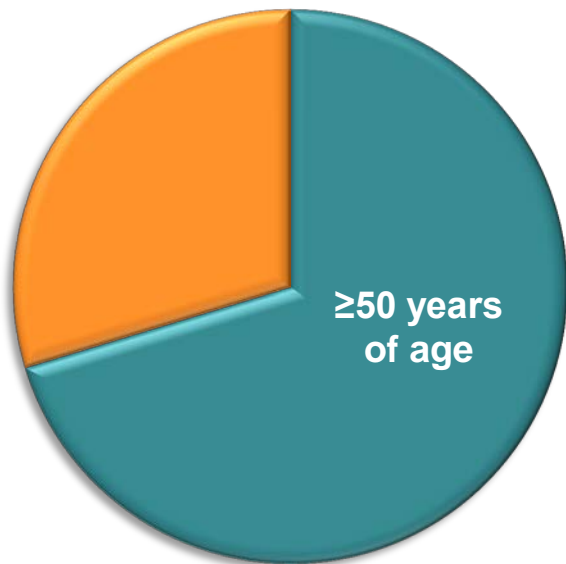


**There is no way to predict when the varicella-zoster virus (VZV) will reactivate, who will develop herpes zoster, how severe any individual case may be, when the pain will occur, or how long the pain may last<sup>1-5</sup>**

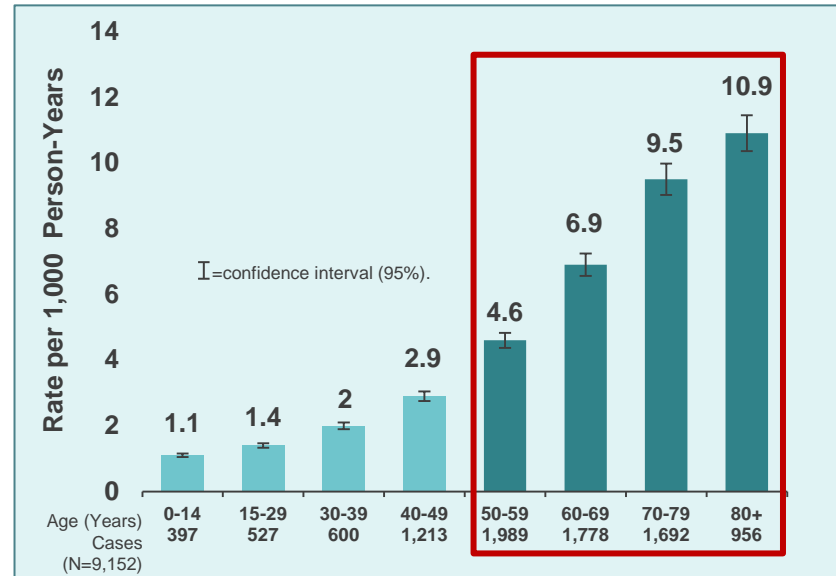
1. Centers for Disease Control and Prevention (CDC). *MMWR Recomm Rep*. 2008;57(RR-5):1-30. 2. Oxman MN. In: Arvin AM, Gershon AA, eds. *Varicella-Zoster Virus: Virology and Clinical Management*. Cambridge, UK: Cambridge University Press; 2000:246-275. 3. Pavan-Langston D. In: Arvin AM, Gershon AA, eds. *Varicella-Zoster Virus: Virology and Clinical Management*. Cambridge, UK: Cambridge University Press; 2000:276-298. 4. Whitley RJ. In: Watson CPN, Gershon AA, eds. *Herpes Zoster and Postherpetic Neuralgia, 2nd Revised and Enlarged Edition*. Amsterdam, the Netherlands: Elsevier Science B.V.; 2001:65-78. 5. Johnson RW. *J Infect Dis*. 2002;186(suppl 1):S83-S90.

# Risk of herpes zoster increases with age<sup>1,2</sup>

Of the estimated 1 million new cases per year in the United States, approximately 71% occur in adults 50 years of age and older<sup>3</sup>



## Risk of Herpes Zoster by Age Group<sup>2,a</sup>



<sup>a</sup>Total number of cases is 9,152.

### After age 50,

- The risk for zoster increases substantially with age.<sup>1,2</sup>
- Risk and severity of zoster increase markedly due to age-related decline in cell-mediated immunity.<sup>4</sup>

1. CDC. *MMWR Recomm Rep.* 2008;57(RR-5):1–30. 2. Insinga RP et al. *J Gen Intern Med.* 2005;20(8):748–753. 3. Yawn BP et al. *Neurology.* 2013;81:928–930. 4. Johnson RW et al. *BMC Med.* 2010;8:37.

# Pain is one of the most debilitating symptoms of zoster, with the potential to occur before, during, or after rash onset<sup>1</sup>

In a 2004 study designed to describe the acute pain of zoster and assess its impact on patients (N=110)<sup>1</sup>:

**96%** experienced acute pain

Of these patients:

**42%** reported that their worst zoster-associated pain was “horrible” or “excruciating”

## Postherpetic neuralgia (PHN) is the most common complication of herpes zoster<sup>2</sup>

- PHN is chronic neuropathic pain lasting for at least 3 months after rash onset<sup>3</sup>:
  - However, the pain may persist beyond that, for months or even years.<sup>2,4</sup>
    - Not everyone who experiences zoster suffers from PHN.<sup>2</sup>
    - The incidence of PHN increases with age.<sup>2</sup>
- Patients have described PHN as burning, throbbing, stabbing, shooting, and/or sharp pain.<sup>2</sup>

1. Katz J et al. *Clin Infect Dis*. 2004;39(3):342–348. 2. Oxman MN. In: Arvin AM, Gershon AA, eds. *Varicella-Zoster Virus: Virology and Clinical Management*. Cambridge, UK: Cambridge University Press; 2000:246–275. 3. Schmader KE. *Clin J Pain*. 2002;18(6):350–354. 4. Johnson RW et al. *J Infect Dis*. 2002;186(suppl 1):S83–S90.

# Zoster can have other serious complications beyond pain<sup>1</sup>

5

## 10% to 25% of zoster patients suffer from ophthalmic zoster<sup>2</sup>

- 50% to 72% of patients who develop ophthalmic zoster will suffer chronic, recurring ocular disease and visual loss.<sup>1</sup>

## Some zoster patients will experience other potentially serious complications<sup>3,4</sup>

- Scarring
- Cranial and motor neuron palsies
- Bacterial superinfection
- Hearing loss, when ear area is involved



## Even before the rash appears, the damage may already be done<sup>5</sup>

- A severe hemorrhagic inflammation occurs in the dorsal root ganglia as the VZV reactivates and replicates.
- VZV causes scarring and loss of nerve cells and fibers long after the rash has healed.

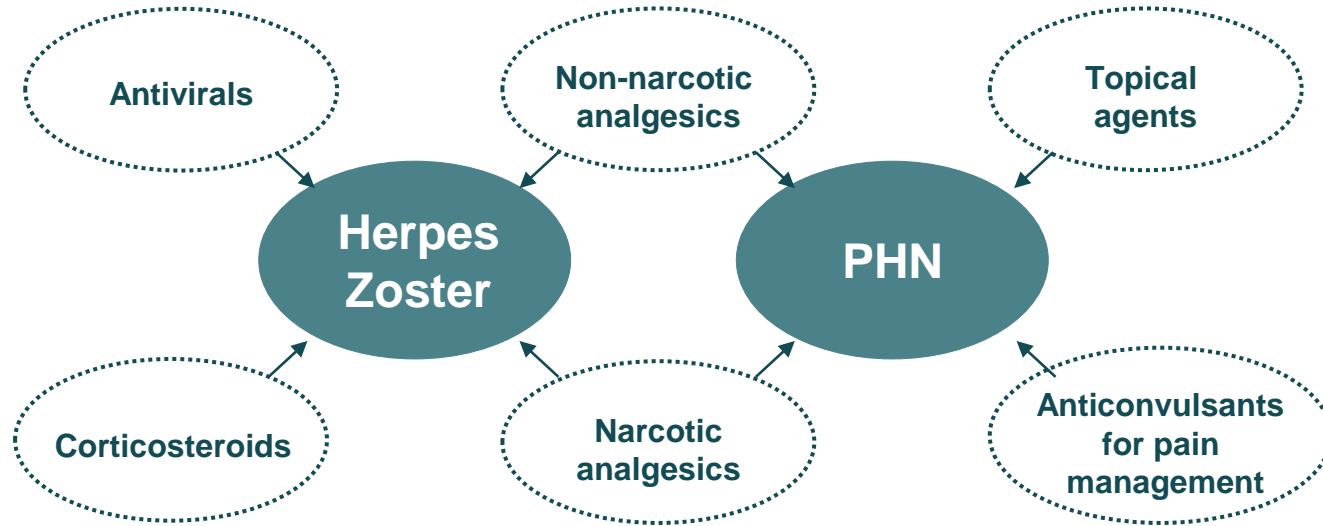


1. Pavan-Langston D. In: Arvin AM, Gershon AA, eds. *Varicella-Zoster Virus: Virology and Clinical Management*. Cambridge, UK: Cambridge University Press; 2000:276–298.  
2. CDC. *MMWR Recomm Rep*. 2008;57(RR-5):1–30. 3. Oxman MN. In: Arvin AM, Gershon AA, eds. *Varicella-Zoster Virus: Virology and Clinical Management*. Cambridge, UK: Cambridge University Press; 2000:246–275. 4. Yawn BP et al. *Mayo Clin Proc*. 2007;82(11):1341–1349. 5. Schmader KE et al. *J Infect Dis*. 2008;197(suppl 2):S207–S215.

# Treating Herpes Zoster and PHN Can Be Difficult

6

- Treatment for herpes zoster and PHN often requires a multifaceted approach<sup>1-3</sup>



- Antiviral therapy for acute herpes zoster should be initiated within 72 hours after the appearance of skin lesions<sup>1-3</sup>
  - Antiviral therapy hastens the resolution of skin lesions but does not significantly reduce the incidence of PHN<sup>1,4</sup>

**Although PHN may resolve over time, current treatments for PHN are largely suboptimal and often accompanied by intolerable side effects.<sup>4,5</sup>**

PHN = postherpetic neuralgia.

1. Cohen JI. *N Engl J Med*. 2013;369:255-263. 2. Johnson RW. *J Dis Infect*. 2002;186(Suppl 1):S83-S90. 3. Harpaz et al. *MMWR*. 2008;57(RR-5):1-30. 4. Chen N et al. *Cochrane Database Syst Rev*. 2014 Feb 6;2:CD006866. doi: 10.1002/14651858.CD006866.pub3. 5. Sacks GM. *Am J Manag Care*. 2013;19(Suppl 1): S3-S9.

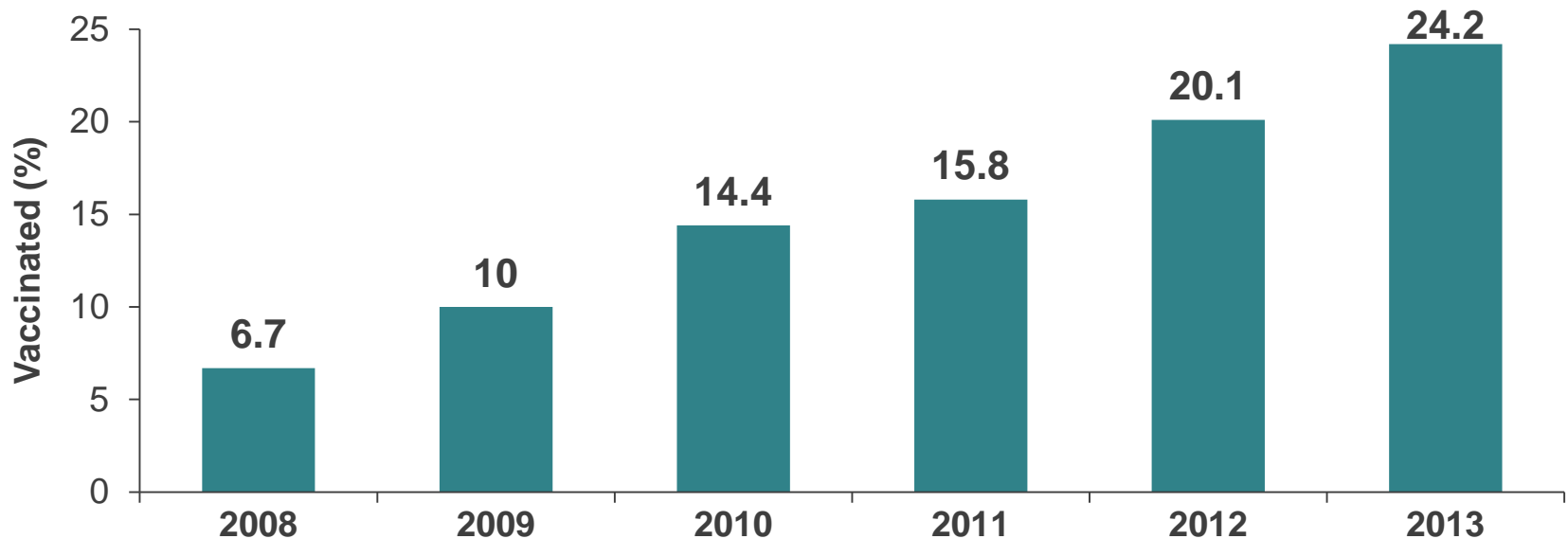


Helping to Protect  
Against  
Herpes Zoster

**ZOSTAVAX<sup>®</sup>**  
Zoster Vaccine Live

Although the vaccination rate for herpes zoster has increased among adults aged 60 years and older, approximately 75% remain unvaccinated<sup>1-5</sup>

Self-reported vaccination rate for adults aged 60 years and older<sup>1-5</sup>



- Only 1.4% of adults aged 50 to 59 years were vaccinated for herpes zoster according to a 2011 survey of self-vaccination rates in a large clinic.<sup>6</sup>

1. CDC. *MMWR Morb Mortal Wkly Rep.* 2014;63(5):85-120. 2. CDC. *MMWR Morb Mortal Wkly Rep.* 2013;62(4):61-76. 3. CDC. *MMWR Morb Mortal Wkly Rep.* 2012;61(4):61-ND57. 4. CDC Web site. NHIS 2009 adult vaccination coverage—the National Health Interview Survey (NHIS). <http://www.cdc.gov/vaccines/imz-managers/coverage/nhis/2009-nhis.html>. Accessed October 6, 2014. 5. CDC. *MMWR Morb Mortal Wkly Rep.* 2015;64(4):95-102. 6. Javed S et al. *Dermatol Online J.* 2012;18(8):2. <http://escholarship.org/uc/item/9n03w07g>. Accessed November 17, 2014.



# An opportunity to help prevent herpes zoster

## ZOSTAVAX® (Zoster Vaccine Live) is indicated for the prevention of herpes zoster in adults 50 years of age and older

### The CDC's ACIP recommendations for zoster vaccination:

- All adults 60 years of age and older should be vaccinated routinely at the first clinical encounter.<sup>1,2</sup>
- Although the vaccine is licensed by the US Food and Drug Administration (FDA) for use among and can be administered to persons 50 years of age and older, the ACIP recommends that vaccination begin at 60 years of age.<sup>2</sup>

### About ZOSTAVAX

ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older. ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia. ZOSTAVAX should not be used for prevention of primary varicella infection (Chickenpox).

### Select Safety Information

Vaccination with ZOSTAVAX does not result in protection of all vaccine recipients.

ZOSTAVAX is contraindicated in: persons with a history of anaphylactic or anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; persons with a history of primary or acquired immunodeficiencies; persons on immunosuppressive therapy; pregnant women or women of childbearing age.



ACIP=Advisory Committee on Immunization Practices.

1. CDC. *MMWR Recomm Rep*. 2008;57(RR-5):1-30. 2. CDC. *MMWR Morb Mortal Wkly Rep*. 2013;62(suppl):1-19.



# Based on results of the ZOSTAVAX Efficacy and Safety Trial (ZEST)<sup>a</sup>

10

## Lower incidence of herpes zoster compared with placebo

In subjects aged  
50-59 years

**70%**

significant reduction of  
the risk of zoster

99 cases in the placebo group (n=11,228) vs  
30 cases in the ZOSTAVAX group (n=11,211) [95% CI: 54-81]

---

PHN was not evaluated in patients aged 50 to 59 years.

### Select Safety Information

- A reduced immune response to ZOSTAVAX was observed in individuals who received concurrent administration of PNEUMOVAX<sup>®</sup>23 (Pneumococcal Vaccine Polyvalent) and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks.
- Serious vaccine-related adverse reactions that have occurred following vaccination with ZOSTAVAX include asthma exacerbation and polymyalgia rheumatica. Other serious adverse events reported following vaccination with ZOSTAVAX include cardiovascular events (congestive heart failure, pulmonary edema). Common adverse reactions occurring in  $\geq 1\%$  of vaccinated individuals during clinical trials include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.

<sup>a</sup>**Study Design for ZEST:** In ZEST, efficacy was evaluated in a placebo-controlled, double-blind study of ZOSTAVAX. 22,439 subjects aged 50 to 59 years were randomized to receive a single dose of either ZOSTAVAX (n=11,211) or placebo (n=11,228) and were monitored for the occurrence of shingles for a median of 1.3 years postvaccination (range, 0 to 2 years).

# Safety profile in patients aged 50 to 59 years

In the ZOSTAVAX Efficacy and Safety Trial (ZEST), the overall incidence of vaccine-related injection-site adverse reactions within 5 days postvaccination was greater for subjects vaccinated with ZOSTAVAX as compared to subjects who received placebo (63.6% for ZOSTAVAX and 14.0% for placebo).

## Injection-site adverse reactions reported in ≥1% of adults who received ZOSTAVAX or placebo within 5 days postvaccination in ZEST

ADVERSE EXPERIENCE	SOLICITED <sup>a</sup>			UNSOLICITED			
	Pain	Erythema	Swelling	Pruritus	Warmth	Hematoma	Induration
<b>ZOSTAVAX</b> (n=11,094) %	53.9	48.1	40.4	11.3	3.7	1.6	1.1
<b>PLACEBO</b> (n=11,116) %	9.0	4.3	2.8	0.7	0.2	1.6	0.0

<sup>a</sup>Solicited on the Vaccination Report Card (VRC).

As with any vaccine, adequate treatment provisions, including epinephrine injection (1:1,000), should be available for immediate use should an anaphylactic/anaphylactoid reaction occur.

### Systemic Adverse Reactions

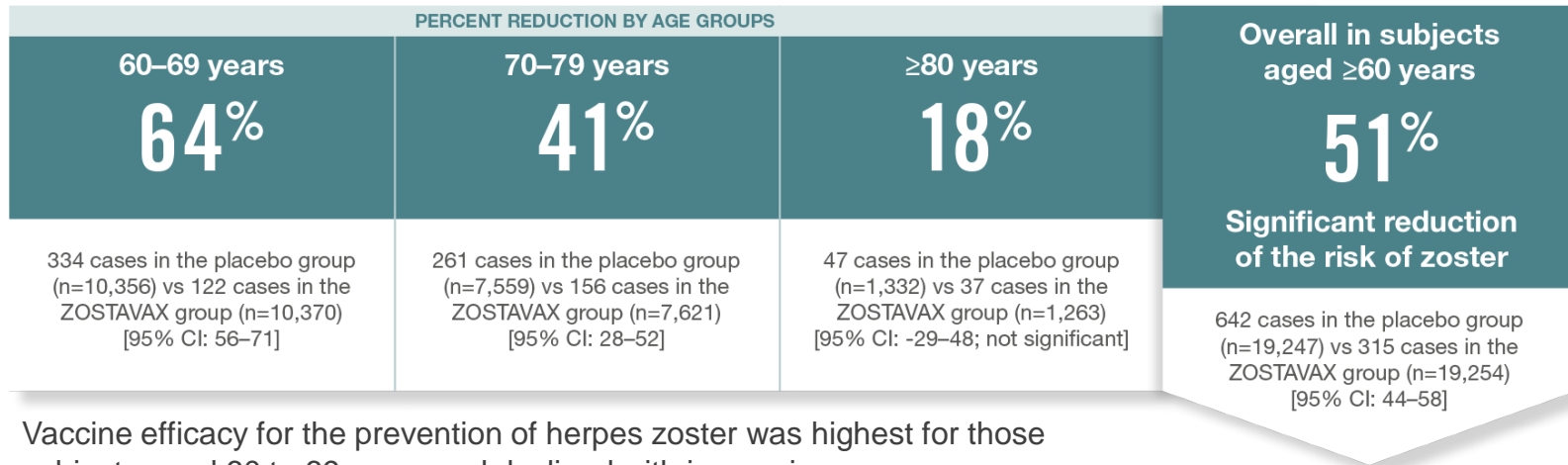
- Systemic adverse reactions and experiences reported during Days 1 to 42 at an incidence of ≥1% in either vaccination group were headache (ZOSTAVAX 9.4%, placebo 8.2%) and pain in the extremity (ZOSTAVAX 1.3%, placebo 0.8%), respectively.
- The overall incidence of systemic adverse experiences reported during Days 1 to 42 was higher for ZOSTAVAX (35.4%) than for placebo (33.5%).

### Serious Adverse Events

- In ZEST, serious adverse events occurred at a similar rate in subjects vaccinated with ZOSTAVAX (0.6%) or placebo (0.5%) from Days 1 to 42 postvaccination.
- In ZEST, an anaphylactic reaction was reported for one subject vaccinated with ZOSTAVAX.

# Based on results of the Shingles Prevention Study (SPS)<sup>a</sup>

## Reduction of herpes zoster incidence compared with placebo



Vaccine efficacy for the prevention of herpes zoster was highest for those subjects aged 60 to 69 years and declined with increasing age.

### Select Safety Information

Vaccination with ZOSTAVAX does not result in protection of all vaccine recipients.

Serious vaccine-related adverse reactions that have occurred following vaccination with ZOSTAVAX include asthma exacerbation and polymyalgia rheumatica. Other serious adverse events reported following vaccination with ZOSTAVAX include cardiovascular events (congestive heart failure, pulmonary edema). Common adverse reactions occurring in ≥1% of vaccinated individuals during clinical trials include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.

<sup>a</sup>**Study Design:** In the SPS, efficacy was evaluated in a placebo-controlled, double-blind clinical trial of ZOSTAVAX. 38,546 subjects aged 60 years or older were randomized to receive a single dose of either ZOSTAVAX (n=19,270) or placebo (n=19,276). Randomization was stratified by age, 60 to 69 and ≥70 years of age. All patients were monitored for the development of zoster for a median of 3.1 years (range, 31 days to 4.90 years).

# Incidence of postherpetic neuralgia (PHN) in SPS<sup>a</sup>

13

Overall in subjects aged  $\geq 60$  years

51%

**Significant reduction of the risk of zoster**

642 cases in the placebo group (n=19,247) vs 315 cases in the ZOSTAVAX group (n=19,254) [95% CI: 44–58]

**In patients aged  $\geq 60$  years who received ZOSTAVAX and developed herpes zoster postvaccination...**

39%

**Overall lower incidence of PHN as compared to those in the placebo group<sup>b</sup>**

PHN was defined as clinically significant zoster-associated pain rated as  $\geq 3$  (on a 0–10 scale), persisting more than 90 days after rash onset.

**The benefit of ZOSTAVAX in the prevention of PHN can be primarily attributed to the effect of the vaccination on the prevention of zoster.**

ZOSTAVAX reduced the incidence of PHN in individuals aged 70 years and older who developed zoster postvaccination.

Vaccine efficacy against PHN in subjects who developed zoster postvaccination was 55% (95% CI: 18–76) in individuals aged 70 to 79 years; 5% (95% CI: -107–56; not significant) in individuals aged 60 to 69 years; and 26% (95% CI: -69–68; not significant) in individuals aged 80 years and older.

The duration of protection beyond 4 years after vaccination with ZOSTAVAX is unknown. The need for revaccination has not been defined, but is currently under study.

<sup>a</sup>**Study Design:** In the SPS, efficacy was evaluated in a placebo-controlled, double-blind clinical trial of ZOSTAVAX. 38,546 subjects aged 60 years or older were randomized to receive a single dose of either ZOSTAVAX (n=19,270) or placebo (n=19,276). Randomization was stratified by age, 60 to 69 and  $\geq 70$  years of age. All patients were monitored for the development of zoster for a median of 3.1 years (range, 31 days to 4.90 years).

<sup>b</sup>Age-adjusted estimate based on age strata (aged 60 to 69 years and  $\geq 70$  years) at randomization.

# Safety profile in patients aged $\geq 60$ years

The Adverse Event Monitoring Substudy (AEMS) of the Shingles Prevention Study (SPS), designed to provide detailed data on the safety profile of the zoster vaccine, used Vaccination Report Cards (VRCs) to record adverse events occurring from Days 0 to 42 postvaccination.

Injection-site reactions<sup>a</sup> in  $\geq 1\%$  of adults who received ZOSTAVAX or placebo within 5 days postvaccination from the AEMS of the SPS

ADVERSE REACTION	SOLICITED <sup>b</sup>			UNSOLICITED		
	Erythema	Pain/Tenderness	Swelling	Hematoma	Pruritus	Warmth
<b>ZOSTAVAX</b> (n=3,345) %	35.6	34.3	26.1	1.6	6.9	1.6
<b>PLACEBO</b> (n=3,271) %	6.9	8.3	4.5	1.4	1.0	0.3

Most injection-site adverse experiences were reported as mild in intensity.

## Systemic Adverse Reactions

- Headache was the only systemic adverse reaction reported on the VRC between Days 0 to 42 by  $\geq 1\%$  of subjects in the AEMS in either vaccination group (ZOSTAVAX 1.4%, placebo 0.8%).

<sup>a</sup>Patients instructed to report adverse experiences on a VRC. <sup>b</sup>Solicited on the VRC.

# Safety profile in patients aged $\geq 60$ years (*continued*)

15

## Serious Adverse Events

- From Day 0 to 42 postvaccination, in the overall study population, serious adverse experiences (SAEs) occurred at a similar rate (1.4%) in subjects vaccinated with ZOSTAVAX or placebo. In the AEMS,<sup>a</sup> the rate of SAEs was increased in the group that received ZOSTAVAX (1.9%) as compared to the placebo group (1.3%) from Day 0 to 42 postvaccination.
- Over the course of the entire study, in the overall study population, investigator-determined, vaccine-related SAEs were reported for 2 subjects vaccinated with ZOSTAVAX (asthma exacerbation and polymyalgia rheumatica) and 3 subjects who received placebo (Goodpasture's syndrome, anaphylactic reaction, and polymyalgia rheumatica).
  - Among reported SAEs in the SPS (Days 0 to 42 postvaccination), serious cardiovascular events occurred more frequently in subjects who received ZOSTAVAX (20 [0.6%]) than in subjects who received placebo (12 [0.4%]) in the AEMS.<sup>a</sup>
  - The frequencies of serious cardiovascular events were similar in subjects who received ZOSTAVAX (81 [0.4%]) and in subjects who received placebo (72 [0.4%]) in the entire SPS study cohort (Days 0 to 42 postvaccination).

<sup>a</sup>Patients instructed to report adverse experiences on a VRC.



Data on file. Merck & Co., Inc.



# Potential Obstacles to Herpes Zoster Vaccination

Plan | Provider  
Patient | Pharmacy

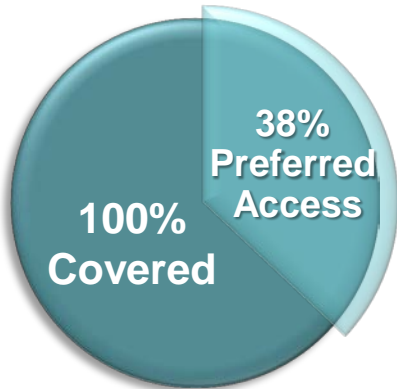


# Providers have concerns about coverage, reimbursement, and patient cost for zoster vaccination<sup>1</sup>

## General concerns about coverage, reimbursement, and patient out-of-pocket (OOP) costs for adult vaccines are highly prevalent among providers responding to a survey in 2012<sup>1</sup>

- Based on a survey conducted in 2010, >50% of surveyed physicians were not aware that the zoster vaccine is covered by Medicare Part D.<sup>2</sup>

## 100% of Medicare Part D plans have ZOSTAVAX® (Zoster Vaccine Live) on formulary as of March 2014, but only 38% of beneficiaries have access on a preferred tier<sup>3,a</sup>



Medicare Part D Plans With Formulary Coverage of the Zoster Vaccine<sup>3,a</sup>

## The amount and availability of reimbursement will depend on a patient's insurance benefit design, including applicable copays, coinsurance, deductibles, and/or limits<sup>3,a</sup>

- Based on a survey conducted in 2010, 43% of surveyed physicians report reimbursement complexity as a major barrier for zoster vaccine use for Medicare Part D.<sup>2</sup>

<sup>a</sup>Formulary data provided by DR/Decision Resources, LLC, and current as of March 2014. © DR/Decision Resources, LLC. All Rights Reserved.)

1. National Vaccine Advisory Committee. *Public Health Rep.* 2012;127(suppl 1):1–42. 2. Hurley LP et al. *Ann Intern Med.* 2010;152(9):555–560. 3. Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package VACC-1114216-0000.

# Benefit complexity may contribute to the confusion about private insurance coverage of the zoster vaccine<sup>1</sup>

18

## Multiple factors may complicate zoster vaccine coverage by private insurance:

- Benefit design—medical vs pharmacy benefit
  - <25% of lives with coverage under the medical benefit also have coverage under the pharmacy benefit.<sup>2</sup>

**Establishing coverage transparency and reducing coverage concerns may increase physician and pharmacist willingness to administer the zoster vaccine and improve patient understanding<sup>1,3</sup>**

- Age—≥60 years vs 50 to 59 years<sup>2,a,b</sup>
  - >97% of adults aged 60 years or older have coverage.
  - But only 33% of those aged 50 to 59 years have coverage.

**Insurance coverage for adults 50 years of age and older offers providers flexibility to exercise their clinical judgment on the use of the zoster vaccine in accordance with FDA-approved uses**

1. Hurley LP et al. *Ann Intern Med.* 2010;152(9):555–560. 2. Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package VACC-1114218-0000. 3. National Vaccine Advisory Committee. *Public Health Rep.* 2012;127(suppl 1):1–42.

# Significant differences in payer benefit designs may dictate how the zoster vaccine is covered

## Medicare

- Zoster vaccine and administration cost is covered under the Part D benefit.<sup>1</sup>
- Most physician offices do not have a direct way to bill Medicare Part D.<sup>1</sup>
- Patient OOP costs range widely<sup>2</sup>
  - Patients often pay the entire cost and wait for reimbursement.<sup>1</sup>
  - Patient costs can be substantial (50%), such as during the donut hole phase.<sup>3</sup>

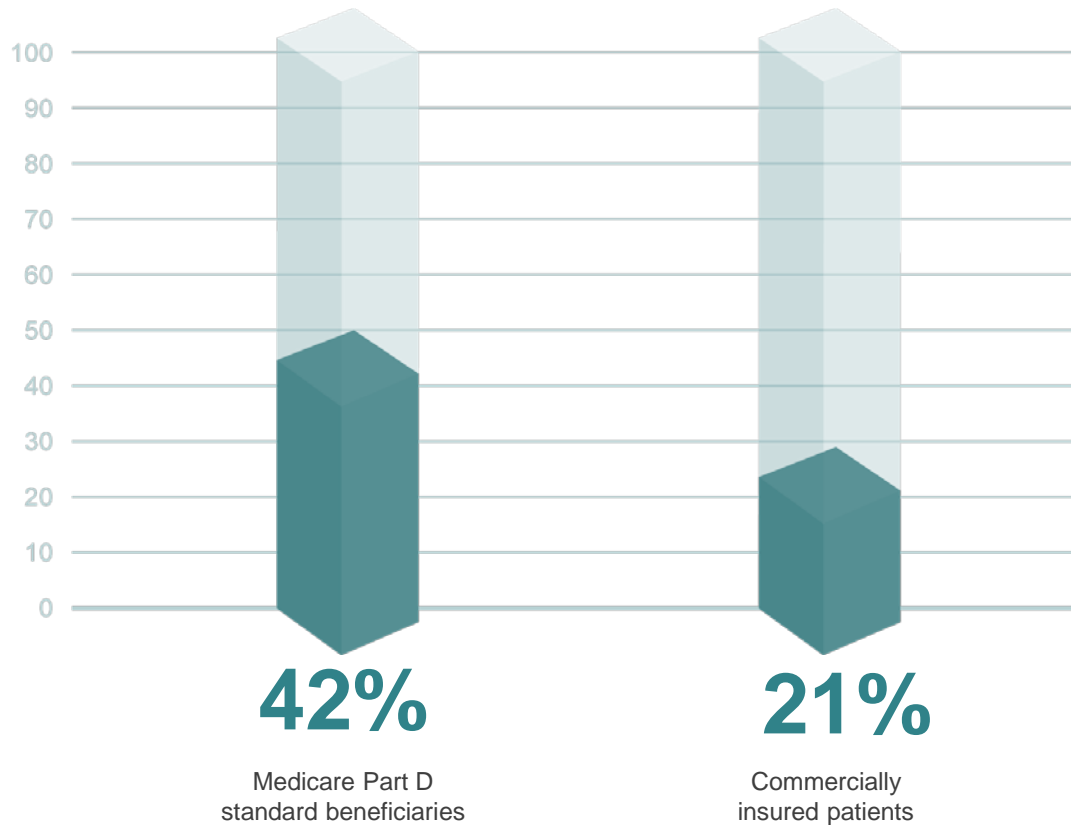
## Private Insurance

- Some patients may have vaccine coverage under the medical benefit only.<sup>4,5</sup>
- Although first-dollar coverage requirements under health care reform may apply to many patients, some may still have cost sharing for vaccinations.<sup>6,7</sup>
- Pharmacies may not have a direct way to bill commercial medical benefits.<sup>4</sup>

1. Hurley LP et al. *Ann Intern Med.* 2010;152(9):555–560. 2. Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package VACC-1083210-0000. 3. Kaiser Family Foundation. The Medicare prescription drug benefit: fact sheet. Published November 19, 2012. <http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>. Accessed August 13, 2013. 4. American Pharmacists Association, Academy of Managed Care Pharmacy. *J Am Pharm Assoc.* 2011;51(6):704–712. 5. Moore KJ et al. *Fam Pract Manag.* 2008;15(8):28–32. 6. The Affordable Care Act and immunization. Healthcare.gov Web site. <http://www.hhs.gov/healthcare/facts/factsheets/2010/09/The-Affordable-Care-Act-and-Immunization.html>. Accessed November 13, 2014. 7. America's Health Insurance Plans. AHIP vaccines and immunization roundtable report: vaccine financing. <http://www.ahip.org/Vaccine-Financing>. Published August 2009. Accessed November 13, 2014.

# OOP cost disparity may lead to a gap in fulfillment between Medicare Part D beneficiaries and commercially insured patients

- Zoster vaccine claim reversal rates (from 2012–2013)



Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package VACC-1083210-0000.

# Lack of physician recommendation and high patient OOP costs remain obstacles to improving zoster vaccination rates

21

- Lack of physician recommendation: According to the 2007 National Immunization Survey (NIS)–Adult, approximately 78% of patients aged ≥60 years said they would get the shingles vaccine if their doctor recommended it.<sup>1,a</sup>
- In a 2010 survey of physicians (n=598), >80% cited cost concerns for patients as a significant barrier for zoster vaccine use.<sup>2,3</sup>
- A study from 2008 found that most primary care physicians believe that their patients would be willing to spend no more than \$30 in OOP costs for zoster vaccination.<sup>4</sup>

## Percentage of medical claims for zoster vaccine below \$30<sup>5,6</sup>

Medicare  
Part D standard  
benefit claims<sup>6</sup>

42%

Commercial  
medical claims<sup>5</sup>

91%

**An opportunity exists to improve vaccination rates by reducing copay burden for patients**

<sup>a</sup>**Study Design:** Subanalysis of data from the 2007 NIS–Adult, a national telephone survey sponsored by the CDC to obtain detailed information regarding adult vaccination coverage. This subanalysis accessed zoster vaccination coverage among persons aged ≥60 years (N=3,662). Of the 3,235 respondents unvaccinated for zoster, 77.8% said they would get the vaccine if recommended by their doctor.<sup>1</sup>

1. Lu PJ et al. *Vaccine*. 2009;27(6):882–887. 2. Hurley LP et al. *Ann Intern Med*. 2010;152(9):555–560. 3. Elkin Z et al. *Cornea*. 2013;32(7):976-981. 4. Hurley LP et al. *J Infect Dis*. 2008;197(suppl 2):S216–S223. 5. Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package VACC-1129930-0000. 6. Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package VACC-1083210-0000.

# Potential challenges to vaccinating eligible patients against herpes zoster in the pharmacy

- The following have been recognized as potential challenges for vaccinations at pharmacies in the United States:

Differences in how claims are covered and adjudicated by commercial and government payers<sup>1</sup>

Complexities in processing claims between medical and pharmacy benefits are obstacles to vaccinations at the pharmacy<sup>2</sup>

Restricted medical group networks or plans may be obstacles to enabling community pharmacists to conduct vaccinations<sup>2,3</sup>

Lack of recognition of pharmacists as health care providers by payers<sup>1</sup>

Variability in state pharmacy regulations<sup>1</sup>

1. American Pharmacists Association, Academy of Managed Care Pharmacy. *J Am Pharm Assoc.* 2011;51(6):704–712. 2. Ko KJ et al. *J Manag Care Pharm.* 2014;20(3):273–282. 3. Uniform Medical Plan Website. Vaccines given by out-of-network providers. <http://www.fuzeqna.com/ump/ext/kb887-vaccines-given-by-outofnetwork-providers?kbidd=887>. Accessed October 23, 2014.

# Ways to Improve Herpes Zoster Vaccination Rates

Plan | Provider  
Patient | Pharmacy

# Steps that may improve herpes zoster vaccination rates

24

## Plan

- **Establish plan designs** to facilitate herpes zoster vaccination as a pharmacy benefit and a medical benefit.
- **Develop pharmacy-based vaccine benefits** using one of these suggested models<sup>1</sup>:
  - Add vaccines/vaccine administration to the list of PBMs' covered products.
  - Allow in-network delivery of vaccines at the pharmacy under the medical benefit.

## Provider

- **Increase awareness and encourage discussion** between physicians and patients about herpes zoster vaccination.
  - Most unvaccinated patients say they would receive the zoster vaccine if their physician recommended it.<sup>2</sup>

PBM=pharmacy benefit manager.



1. Ko KJ et al. *JMCP*. 2014;20(3):273–282f. 2. Lu PJ et al. *Vaccine*. 2009;27(6):882–887.



# Steps that may improve herpes zoster vaccination rates (continued)

25

## Patient

- **Increase awareness** about vaccination.
  - >70% of surveyed adults are unaware of recommended and/or approved uses of the herpes zoster vaccine.<sup>1,2</sup>
- **Encourage** patients to ask their providers about vaccination.
- **Educate** patients about vaccination coverage (eg, first-dollar) and appropriate administrators of vaccines.<sup>3</sup>

## Pharmacy

- Recognize and promote **pharmacists as immunizers**, as recommended by the APhA and AMCP.<sup>4</sup>
- **Process adult vaccination claims using current pharmacy information management systems.**<sup>3</sup>
- Require that the health plans/PBMs **attribute the claim to the appropriate benefit.**<sup>3</sup>

1. Joon Lee T et al. *J Am Board Fam Med.* 2013;26(1):45–51. 2. Javed S et al. *Dermatol Online J.* 2012;18(8):2. 3. Ko KJ et al. *JMCP.* 2014;20(3):273–282.

4. American Pharmacists Association, Academy of Managed Care Pharmacy. *J Am Pharm Assoc.* 2011;51(6):704–712.

# Important Information About ZOSTAVAX® (Zoster Vaccine Live)

26

## Select Safety Information

- Vaccination with ZOSTAVAX does not result in protection of all vaccine recipients.
- ZOSTAVAX is contraindicated in: persons with a history of anaphylactic or anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; persons with a history of primary or acquired immunodeficiencies; persons on immunosuppressive therapy; pregnant women or women of childbearing age.
- A reduced immune response to ZOSTAVAX was observed in individuals who received concurrent administration of PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent) and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks.

# Important Information About ZOSTAVAX<sup>®</sup> (Zoster Vaccine Live) (*continued*)

27

## Select Safety Information (*continued*)

- Serious vaccine-related adverse reactions that have occurred following vaccination with ZOSTAVAX include asthma exacerbation and polymyalgia rheumatica. Other serious adverse events reported following vaccination with ZOSTAVAX include cardiovascular events (congestive heart failure, pulmonary edema). Common adverse reactions occurring in  $\geq 1\%$  of vaccinated individuals during clinical trials include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.
- Transmission of vaccine virus may occur between vaccinees and susceptible contacts.
- Deferral should be considered in acute illness (for example, in the presence of fever) or in patients with active untreated tuberculosis.

**Before administering ZOSTAVAX, please read the accompanying Prescribing Information. The Patient Information also is available.** For additional copies of the Prescribing Information, please call 800-672-6372, visit [MerckVaccines.com](http://MerckVaccines.com)<sup>®</sup>, or contact your Merck representative.

