

Important Facts About Fluzone® High-Dose (Influenza Virus Vaccine) for Patients 65 Years of Age and Older

Influenza Risks in Our Seniors Create a Clinical Gap in This Population

- People 65 years of age and older are affected disproportionately by influenza-related morbidity and mortality¹⁻⁴; each year in the United States, this population accounts for approximately:
 - two-thirds of the 55,000 to 431,000 influenza-related hospitalizations reported¹
 - 90% of the 3000 to 49,000 influenza-related deaths reported^{2,3}
- Equally concerning, after immunization with a standard-dose influenza vaccine:
 - the rate of breakthrough influenza infection among people 65 years of age and older has been shown to be higher than in younger adults^{2,5}
 - older adults mount less of an antibody response to hemagglutinin (an established correlate of protection against influenza) compared to younger adults⁶

Fluzone High-Dose Vaccine Is Available to Address the Clinical Gap in Patients 65 Years of Age and Older

- Fluzone High-Dose vaccine contains an increased amount of antigen⁷
- The high-dose formulation demonstrates a superior immune response over Fluzone (Influenza Virus Vaccine)^{7,a}
 - generating higher antibody levels (geometric mean antibody titers)
 - inducing higher seroconversion rates
- Early adopters have documented the successful implementation of Fluzone High-Dose vaccine for use in their patients 65 years of age and older and have indicated they plan to use Fluzone High-Dose vaccine as their standard of care in 2011-2012
- Fluzone High-Dose vaccine is supplied as a preservative-free, single-dose, prefilled syringe containing 0.5mL of vaccine for intramuscular injection

The Food and Drug Administration (FDA) Licensed Fluzone High-Dose Vaccine Based on its Robust Immune Response in People 65 Years of Age and Older

- Fluzone High-Dose vaccine was granted accelerated approval by the FDA due to its potential to address the unmet medical need for a more robust influenza vaccine for older adults, based on a surrogate endpoint (ie, immune response to a key component of the influenza virus)^a
- Many other examples of accelerated approvals based on surrogate endpoints exist, including the following:
 - as a result of the medical community's belief that tumor shrinkage produced by a chemotherapeutic agent is reasonably likely to predict a clinical benefit, some of these agents have been granted accelerated approval⁸
 - human immunodeficiency virus (HIV) treatments that demonstrate reductions in viral load (a surrogate endpoint for HIV disease) may also be granted accelerated approval^{8,9}
 - statins are used to help prevent heart disease by lowering cholesterol levels in the blood; it has become accepted that lower total cholesterol levels are correlated with a lower risk of death from heart disease¹⁰

The Advisory Committee on Immunization Practices (ACIP) Recommends Fluzone High-Dose Vaccine as an Option

- According to an ACIP guidance published in April 2010, Fluzone High-Dose vaccine is a recommended option for patients 65 years of age and older¹¹; of note:
 - the ACIP does not typically express a preference for one influenza vaccine over another as it could result in unintended shortages
 - in February 2011, the ACIP included Fluzone High-Dose vaccine as an option for this age group in its Recommended Adult Immunization Schedule¹²

Adoption of Fluzone High-Dose Vaccine Can Be Cost Effective

- When the incremental cost of the newer formulation is weighed against the potential to avoid hospitalization, Fluzone High-Dose vaccine can be shown to be cost effective:
 - one way to evaluate the potential cost-effectiveness of adopting an influenza vaccine is to weigh the cost of immunization against the cost of an influenza-related hospitalization; the average cost of an influenza-related hospitalization is \$11,451.50^{13,b}
- When considering the actual cost to you of Fluzone High-Dose vaccine, it is critical to take into account that this vaccine is a covered benefit under Medicare Part B
- CPT^{®c} code 90662 was created specifically for provider reimbursement for Fluzone High-Dose vaccine:
 - all 15 Medicare Administrative Carriers recognize this code and are processing claims for Fluzone High-Dose vaccine
 - some private payers are adding CPT code 90662 at this time because they also need to make other coding changes prior to the 2011-2012 influenza season

Taking Both Benefits and Risks Into Account, Fluzone High-Dose Vaccine Should Be Adopted Because of These Key Points

- People 65 years of age and older are more susceptible to influenza-related complications¹⁻⁴ and have reduced antibody response to standard-dose influenza vaccines^{2,5}
- Fluzone High-Dose vaccine has been shown to produce higher antibody levels, compared to Fluzone vaccine, against the subtypes A and type B strains contained in the vaccines⁷; this increase in antibodies may provide better protection for people 65 years of age and older against influenza
- The FDA licensed Fluzone High-Dose vaccine based on its robust immune response in people 65 years of age and older, granting the vaccine an accelerated approval^a
- The ACIP endorses Fluzone High-Dose vaccine as a recommended influenza vaccine option for patients 65 years of age and older^{11,12}
- Adoption can be cost effective: Fluzone High-Dose vaccine is a covered benefit under Medicare Part B. Furthermore, using 2003 dollars, the prevention of just 1 hospitalization¹³ can neutralize the incremental cost of the newer formulation for 763 patients

Call to Action

- Once Fluzone High-Dose vaccine is adopted, promptly effect the change, eg, create a standing order that includes Fluzone High-Dose vaccine as the default vaccine for people 65 years of age and older

Important Safety Information

Indication

Fluzone Vaccine

Fluzone vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Fluzone High-Dose Vaccine

Fluzone High-Dose vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. This indication is based on the immune response elicited by Fluzone High-Dose vaccine; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine.

Safety Information

Fluzone and Fluzone-High Dose Vaccines

The most common local and systemic adverse reactions to Fluzone and Fluzone High-Dose vaccines include soreness, pain, and swelling at the vaccination site; fever, headache, malaise, and myalgia. Other adverse reactions may occur. Fluzone and Fluzone High-Dose vaccines should not be administered to anyone with a history of hypersensitivity to any vaccine component, including eggs, egg products, or thimerosal (the only presentation that contains thimerosal is the Fluzone vaccine multi-dose vial). The decision to give Fluzone or Fluzone High-Dose vaccine should be based on the potential benefits and risks, especially if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine. The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. Vaccination with Fluzone or Fluzone High-Dose vaccine may not protect all individuals.

^a This indication is based on the immune response elicited by Fluzone High-Dose vaccine; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine.⁷

^b 2003 dollars.

^c CPT = Current Procedural Terminology is a registered trademark of the American Medical Association.

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