

### Fluzone High-Dose Sole Source Clinical Justification

Individuals 65 years old and greater make up 90% of the deaths associated with influenza each year. It has been estimated that over 225,000 persons are hospitalized and 36,000 die due to influenza and resultant complications annually in the US. Vaccination against influenza is the single best way to decrease morbidity and mortality due to influenza infection.

While influenza vaccine has been shown to be highly effective in young, otherwise healthy persons, influenza vaccine is less effective in older persons. At least one reason for this difference is that influenza vaccine is less immunogenic in persons at the extremes of age and in those with underlying health conditions<sup>1</sup>. Since the 1970s research has been performed to determine ways to make the influenza vaccine more immunogenic. One simple solution has been to increase the amount of influenza virus antigen in the vaccine

Reasonable evidence exists to suggest that high dose vaccine will provide protection superior to standard dose. Use may prevent some hospitalizations and deaths.

Fluzone High-Dose is the only high-dose seasonal influenza vaccine commercially available in the United States and is a sole source product of Sanofi Pasteur. Healthcare professionals must have every tool accessible to prevent avoidable influenza infections in the elderly, and Fluzone High-Dose is a vital component of that strategy.

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Date 1/13/2014

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<sup>1</sup> Goodwin K, et al. *Vaccine* 2006;24:1159-69..