

# CENTERS FOR DISEASE CONTROL AND PREVENTION MORBIDITY AND MORTALITY WEEKLY REPORT OCTOBER 2012

## Advisory Committee On Immunization Practices (ACIP) Recommendations Regarding The Use Of 13-Valent Pneumococcal Conjugate Vaccine And 23-Valent Pneumococcal Polysaccharide Vaccine For Adults With Immunocompromising Conditions

### INDICATION AND IMPORTANT INFORMATION

- **Prevnar 13<sup>®</sup> is a vaccine indicated for adults 50 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. Indication is based on immune responses**
- **The Prevnar 13<sup>®</sup> Prescribing Information emphasizes that there are no data on the safety and effectiveness of Prevnar 13<sup>®</sup> when administered to immunocompromised individuals**
- **Immunocompromised individuals or individuals with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody response**

Pfizer does not recommend the use of Prevnar 13<sup>®</sup> in immunocompromised individuals or individuals 18 through 49 years of age. Prevnar 13<sup>®</sup> is not approved by the Food and Drug Administration for immunocompromised individuals or for individuals 18 through 49 years of age. Pfizer is providing a copy of these ACIP recommendations so that health care professionals may use this information to make an informed medical judgment.

Please see additional Indications, Limitations of Use and Effectiveness, and additional Important Safety Information inside, and accompanying full Prescribing Information.



**Prevnar 13<sup>®</sup>**  
Pneumococcal 13-valent Conjugate Vaccine  
(Diphtheria CRM<sub>197</sub> Protein)

# Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults With Immunocompromising Conditions: Recommendations of the ACIP:

## ACIP Recommendations for Pneumococcal Vaccine–Naïve Individuals<sup>1</sup>:

- Adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received 13-valent pneumococcal conjugate vaccine (PCV13) or 23-valent pneumococcal polysaccharide vaccine (PPSV23), should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later
- Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions
- Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of PPSV23 at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose

## ACIP Recommendations for Individuals Previously Vaccinated With PPSV23<sup>1</sup>:

- Adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, who previously have received ≥1 doses of PPSV23 should be given a PCV13 dose ≥1 year after the last PPSV23 dose was received
- For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23

## IMPORTANT INFORMATION ABOUT THE PRESCRIBING INFORMATION FOR PREVNAR 13<sup>®</sup>

- The Prevnar 13<sup>®</sup> Prescribing Information emphasizes that there are no data on the safety and effectiveness of Prevnar 13<sup>®</sup> when administered to immunocompromised individuals:
  - Data on the safety and effectiveness of Prevnar 13<sup>®</sup> when administered to immunocompromised individuals, including those at higher risk for invasive pneumococcal disease (eg, individuals with congenital or acquired splenic dysfunction, HIV infection, malignancy, hematopoietic stem cell transplant, nephrotic syndrome), are not available
  - Immunocompromised individuals or individuals with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody response
- Prevnar 13<sup>®</sup> is not approved by the Food and Drug Administration for immunocompromised individuals or for individuals 18 through 49 years of age

## INDICATIONS

- Prevnar 13<sup>®</sup> is a vaccine indicated for active immunization for the prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
- In adults 50 years and older for pneumococcal pneumonia and invasive disease. Indication is based on immune responses
- In children 6 weeks through 17 years for invasive disease caused by the 13 serotypes, and for children 6 weeks through 5 years of age for otitis media caused by 7 of the 13 serotypes only (4, 6B, 9V, 14, 18C, 19F, and 23F)

## Limitations of Use and Effectiveness

- Prevnar 13<sup>®</sup> will only help protect against *S pneumoniae* serotypes in the vaccine
- Effectiveness when administered <5 years after pneumococcal polysaccharide vaccine is not known

## IMPORTANT SAFETY INFORMATION

- Severe allergic reaction (eg, anaphylaxis) to any component of Prevnar 13<sup>®</sup> or any diphtheria toxoid–containing vaccine is a contraindication
- Immunocompromised individuals or individuals with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody response
- In adults, antibody responses to Prevnar 13<sup>®</sup> were diminished when given with inactivated Influenza Virus Vaccine
- In adults, the commonly reported solicited adverse reactions were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle or joint pain, decreased appetite, chills, or rash
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Vaccination of premature infants should be based on the infant’s medical status, and the potential benefits and risks
- In infants and toddlers, the most commonly reported serious adverse events were bronchiolitis (0.9%), gastroenteritis (0.9%), and pneumonia (0.9%)
- In infants and toddlers, the most commonly reported solicited adverse reactions were injection site tenderness, redness, or swelling, irritability, decreased appetite, decreased or increased sleep, and fever

**Please see accompanying full Prescribing Information.**



**Please see Indications, Limitations of Use and Effectiveness, and Important Safety Information inside, and accompanying full Prescribing Information.**

**Reference: 1.** Centers for Disease Control and Prevention. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 2012;61(40):816-819.



PREVNAR 13 is a registered trademark of Wyeth LLC.

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