

## Prevnar<sup>™</sup> 13 (pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 protein]) – Expanded Indication

- On July 12, 2016, Pfizer announced the FDA approval of Prevnar 13 (pneumococcal 13-valent conjugate vaccine [diphtheria CRM<sub>197</sub> protein]) for active immunization for the prevention of pneumonia and invasive disease caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults 18 years of age and older.
  - Previously, this indication was approved for use in adults 50 years of age and older.
- Prevnar is also approved for the following:
  - Children 6 weeks through 17 years of age (prior to the 18<sup>th</sup> birthday) for the prevention of invasive disease caused by 13 *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.
  - Children 6 weeks through 5 years of age (prior to the 6<sup>th</sup> birthday) for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F. No otitis media efficacy data are available for serotypes 1, 3, 5, 6A, 7F, and 19A.
- Prevnar 13 does not protect against disease caused by S. pneumoniae serotypes that are not in the vaccine.
- The approval of the expanded indication is based on data from a clinical study which demonstrated noninferiority between the immunogenicity of Prevnar 13 in adults aged 18 through 49 years to the immunogenicity of Prevnar 13 in adults aged 60 through 64 years of age.
- Prevnar 13 is administered as a single intramuscular injection in adults ≥ 18 years of age.
- Refer to the current <u>Centers for Disease Control and Prevention immunization schedules</u> for adult and pediatric pneumococcal vaccine recommendations.



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