Prevnar™ 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 CRM197 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 18th 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 6th 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 non-inferiority 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 [Centers for Disease Control and Prevention immunization schedules](https://www.cdc.gov/vaccines/schedules/hcp/imls.html) for adult and pediatric pneumococcal vaccine recommendations.