

CONTAGIOUS COMMENTS

Department of Epidemiology

New Pneumococcal Conjugate Vaccine (PCV13) Licensed; Expands Protection Against Invasive Pneumococcal Disease for Infants

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On February 24, 2010, the FDA licensed a new pneumococcal conjugate vaccine (Pneumovax 13™, [PCV13], Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.) for children 6 weeks through 71 months of age. The same day, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention recommended its use in infants and children. PCV13 will replace Pneumovax (PCV7) which was licensed in 2000. In addition to the 7 pneumococcal serotypes in PCV7 (4, 6B, 9V, 14, 18C, 19F and 23F), the new vaccine contains capsular polysaccharides from 6 additional serotypes of pneumococcus (1, 3, 5, 6A, 7F and 19A). PCV7 was highly effective and its use resulted in a 99% decrease in invasive pneumococcal disease (IPD) due to vaccine serotypes among children < 5 years of age. However IPD due to non vaccine serotypes has increased. In 2007, over 60% of remaining IPD cases in US children were caused by one of the 6 additional serotypes that are included in PCV13. Serotype 19A is the most common and is frequently antibiotic resistant, so its inclusion in the new PCV13 vaccine was particularly important.

The safety of PCV13 was evaluated in 13 clinical trials in which over 4,700 infants and toddlers received PCV13 and over 2,700 children received PCV7. PCV13 was safe and immunogenic, with local injection site reactions being reported in 30% of children. Moderate fever of >39° but ≤40° was seen in 3-4% of children. The rates of solicited local and systemic reactions were similar in the PCV13

and PCV7 groups. ***When will PCV13 be available and are there adequate supplies?***

The company began shipping PCV13 in the second half of March and it should be available in offices by the time of this publication since over 8 million doses were ready for shipment to US children. Twenty million doses are filled for global supply. Vaccine is also available through the VFC program..

What will be the cost of the new vaccine and is it covered by the Vaccine Injury Compensation Program?

The company verbally stated at the recent ACIP meeting that they expect the cost to be \$108 per dose for the private market. The vaccine is VFC approved and the VFC price is currently being negotiated. Pneumococcal conjugate vaccines are covered by the Vaccine Injury Compensation Program.

What will happen to my current stock of PCV7?

The company will arrange for PCV7 stock to be returned to them and the provider will be given credit for those doses when purchasing PCV13. PCV 13 will then become the standard vaccine in the provider's office. VFC sites have been decreasing their inventories of Pneumovax in anticipation of the licensure of PCV13.

Is there a new infant immunization schedule for this vaccine?

No, the same infant immunization schedule that was recommended for PCV7 should be

used for PCV13 for children who have not received previous doses of PCV7 or PCV13. Four doses are recommended at 2, 4, 6, and 12-15 months of age. Catch-up schedules for unvaccinated healthy infants and children are identical to those recommended for PCV7, except for children with underlying medical conditions, where the upper age limit is 71 months.

Should children who are fully immunized with PCV7 be given a dose of PCV13?

Yes, the ACIP voted on February 24 to recommend that **healthy** children 14 months through 59 months of age who are **fully immunized** with PCV7 receive a single dose of PCV13 (referred to as a “supplemental” dose) to elicit antibodies against the 6 additional serotypes. This dose should be given at the next medical visit of the child and no active recall is recommended. A minimum interval of 8 weeks is recommended between the last dose of PCV7 and the supplemental dose of PCV13. For children fully immunized with PCV7 that have **underlying medical conditions** that put them at higher risk of pneumococcal disease, the supplemental dose should be given from 14 through 71 months of age,.

Are there any recommendations for use of this new vaccine in older children who may be high risk for invasive pneumococcal disease?

PCV13 was licensed by the FDA for use in infants and children 6 weeks through 71 months of age and data regarding safety and immunogenicity of PCV13 are not available for older children. However, the ACIP did approve a permissive statement for older children who are high risk for invasive pneumococcal disease stating that providers “may administer” a dose of PCV13 to children 6 through 18

years of age with Sickle Cell Disease, anatomic or functional asplenia, HIV or other immunocompromising condition or presence of cochlear implant or CSF leak.

In addition to receiving PCV13, children 2 through 18 years of age with underlying medical conditions that increase their risk of invasive pneumococcal disease should receive the 23 valent pneumococcal polysaccharide vaccine (PPSV23) at age 2 years, with a minimum interval of 8 weeks after the last dose of PCV13. Doses of PCV13 should be completed before PPSV23 is given. PPSV23 can be given from 2 through 18 years of age, but should be given as soon as possible after age 2 years. A single booster dose of PPSV23 is recommended 5 years after the first dose in children with sickle cell disease, anatomic or functional asplenia, HIV infection or other immunocompromising condition. No more than 2 doses of PPSV23 are recommended at this time.

Where can I find more information?

ACIP provisional recommendations are available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm> The AAP Committee on Infectious Diseases has updated its recommendations for prevention of pneumococcal disease for use by AAP membership and their recommendations are harmonized with the CDC recommendations. AAP recommendations become official after approval by the AAP Board of Directors. These will be published in AAP News and are available electronically at Red Book Online. An AAP policy statement will be published in *Pediatrics*. PCV13 licensure information is available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm201667.htm>

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