



Important Information from the San Antonio Metropolitan Health District (SAMHD)

March 29, 2010

Important Information on Pneumococcal Conjugate Vaccines (Prevnar[®])

ACIP Provisional Recommendations for 13-Valent Pneumococcal Conjugate Vaccine (PCV13)

On February 24, 2010, the Advisory Committee on Immunization Practices (ACIP) voted on recommendations for use of 13-valent Pneumococcal Conjugate Vaccine (Prevnar[®], PCV13) among infants and children. PCV13 was licensed for the prevention of invasive pneumococcal serotypes covered by the vaccine and for prevention of otitis media caused by serotypes in the 7-valent pneumococcal conjugate vaccine formulation (PCV7). The ACIP recommends PCV13 for all children 2 through 59 months of age and for children 60 through 71 months of age who have underlying medical conditions that increase their risk of pneumococcal disease or complications.

SAMHD recommends the following VFC-eligible groups receive PCV13:

- All children at least six weeks of age through 59 months of age.
- Children 60-71 months of age who have underlying medical conditions that increase their risk of pneumococcal disease or complications, such as chronic heart and pulmonary diseases, diabetes, splenic dysfunctions, immunocompromised disorders, etc
- Children 6 through 18 years of age who are at increased risk for invasive pneumococcal disease because of sickle cell disease, HIV-infection, or other immunocompromising condition. These children should receive a single dose of PCV13 regardless if they have had PCV7 or PPSV23 in the past.
- Children 14 through 59 months of age who have received 4 doses of PCV7 or other age-appropriate, complete PCV7 schedule (fully vaccinated with PCV7) are recommended to receive a single supplemental dose of PCV13 given at least 8 weeks after the last dose of PCV7.

The PCV13 vaccine should be available from the SAMHD VFC program in time for your April orders. In the event that PCV7 is the only pneumococcal conjugate vaccine available in provider offices, that vaccine should be provided to children and infants who are due for vaccination. These children should complete their series with PCV13 at subsequent visits.

Because of potential confusion in using different vaccine products for routine and catch-up immunization, the ACIP recommends the following schedule:

Recommended routine vaccination schedule for Infants and Children who have not previously received PCV7 or PCV13

Age at first dose (mos)	Primary PCV13 series*	PCV13 booster dose†
2--6	3 doses	1 dose at age 12--15 mos
7--11	2 doses	1 dose at age 12--15 mos
12--23	2 doses	---
24--59 (healthy children)	1 dose	---
24--71 (Children with certain chronic diseases or immunocompromising conditions)	2 doses	---

* Minimum interval between doses is 8 weeks except for children vaccinated at age <12 months for whom minimum interval between doses is 4 weeks. Minimum age for administration of first dose is 6 weeks.

† Given at least 8 weeks after the previous dose.

Recommended transition schedule from PCV7 to PCV13 vaccination among infants and children, according to number of previous PCV7 doses received

Infant series			Booster dose	Supplemental PCV13 dose
2 mos	4 mos	6 mos	≥12 mos*	14--59 mos†
PCV7	PCV13	PCV13	PCV13	---
PCV7	PCV7	PCV13	PCV13	---
PCV7	PCV7	PCV7	PCV13	---
PCV7	PCV7	PCV7	PCV7	PCV13

* No additional PCV13 doses are indicated for children age 12--23 months who have received 2 or 3 doses of PCV before age 12 months and at least 1 dose of PCV13 at age ≥12 months.

† For children with underlying medical conditions (see Table 1), a single supplemental PCV13 dose is recommended through age 71 months

Further details about the routine pneumococcal conjugate vaccination schedule are available from the ACIP VFC Resolution at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0210-pneumo-508.pdf>

All VFC providers are strongly encouraged to use up as much of your PCV7 inventory as possible before commencing the PCV13 schedule. If you have an abundance of unused PCV7 vaccine that you would like to return to McKesson for replacement PCV13 vaccine, you must contact SAMHD Vaccine Management at 207-4015 by April 9th to request a return shipping label. Doses returned to McKesson by May 1st will be eligible for replacement as part of Centers for Disease Control and Prevention (CDC) operating inventory.

As soon as an updated Vaccine Information Statement (VIS) for PCV13 is available, it may be found at: <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. In the meantime, please use the current VIS and supplement it with manufacturer's package insert or any other materials, written or oral, that are appropriate. Adverse events after receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System at: <http://vaers.hhs.gov>. CDC has posted additional information on Rotarix vaccine at: <http://www.cdc.gov/vaccines/vpd-vac/rotavirus/rotarix-providers.htm>.

Urgent Recall of Privately Purchased Pneumococcal 7-Valent Conjugate Vaccine

Pfizer Pharmaceuticals (formerly Wyeth Vaccines) has issued a voluntary recall of four lots of privately sold (non-VFC) Pneumococcal 7-Valent Conjugate (PCV7, Prevnar[®]) vaccine. During a routine physical inspection of Prevnar[®] pre-filled syringes, it was determined that a potential exists for syringes to have been distributed with a rubber formulation in the syringe tip caps that was not approved for use with this vaccine. A medical assessment was performed and concluded that the affected syringes presented no health or safety risk to patients. Further, there would be no expected loss of potency and no need to revaccinate children who may have received a dose of Prevnar[®] from an affected syringe.

Affected lots and expiration dates of privately sold Prevnar[®] PCV7 vaccine:

- E25197 (Exp 10/13)
- E28211 (Exp 10/13)
- E37556 (Exp 10/13)
- E38749 (Exp 11/13)

Please remove these lots immediately from use and contact Stericycle Inc. @ 1-800-668-4391 to request a Return Kit.

If you have vaccine ordering questions, please contact Anthony Johnson at 207-4015; or for other VFC questions, please contact Kenya Wilson, MA at 207-3974.

SAMHD thanks you for your continued efforts to protect our community.