

**Vaccines for Children (VFC) Program
13-Valent Pneumococcal Conjugate Vaccine (PCV13)
Vaccine Summary
March 11, 2010**

Iowa Vaccines for Children Program Implementation

Effective March 19, 2010, 13-valent pneumococcal conjugate vaccine (PCV13) will be available through the VFC Program and will replace the current 7-valent pneumococcal conjugate vaccine (PCV7) manufactured Pfizer, formerly Wyeth. PCV13 vaccine will be available to order from the VFC Program effective March 11, 2010.

Prevnar Vaccine Recommendations

Food and Drug Administration (FDA) – On February 24, 2010, the FDA approved PCV13 as a four dose schedule for infants and children 2 through 71 months of age.

ACIP – On February 24, 2010, The Advisory Committee on Immunization Practices voted on recommendations for use of the new PCV13 among infants and children. 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. PCV13 vaccine can be administered at the same visit when other age appropriate vaccines are provided.

The Morbidity and Mortality Weekly Report (MMWR), Licensure of a 13-Valent Pneumococcal Conjugate Vaccine (PCV13) and Recommendations for Use Among Children, Advisory Committee on Immunization Practices (ACIP), 2010 is available at

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm?s_cid=mm5909a2_e .

Recommended Schedule for PCV13 Vaccine

1. Infants and children who have not previously received PCV7 or PCV13
 - The ACIP recommendation for use of PCV13 and the immunization schedules for infants and toddlers 2 through 59 months of age who have not received any prior PCV7 or PCV13 doses are the same as those previously published for PCV7 with PCV13 replacing PCV7 for all doses.

Infants 2 through 6 months of age

- PCV13 is recommended as a 4-dose series at 2, 4, 6, and 12 through 15 months of age. Infants receiving their first dose at age ≤ 6 months should receive 3 doses of PCV13 at intervals of approximately 8 weeks (the minimum interval is 4 weeks). Minimum age for administration of first dose is 6 weeks. The fourth dose is recommended at age 12 through 15 months and should be given at least 8 weeks after the third dose.

Unvaccinated children 7 months of age and older

Infants 7 through 11 months of age

- Three doses are recommended. The first 2 doses should be given with an interval of at least 4 weeks between doses. The third dose should be given at age 12 through 15 months, at least 8 weeks after the second PCV13 dose.

Children 12 through 23 months of age

- Two doses are recommended, with an interval of at least 8 weeks between doses.

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Children 24 months of age and older

- Unvaccinated healthy children 24 through 59 months of age should receive a single dose of PCV13. Unvaccinated children 24 through 71 months of age with underlying medical conditions should receive 2 doses of PCV13 with an interval of at least 8 weeks between doses.

2. Children incompletely vaccinated with PCV7 or PCV13

Children <24 months of age

- Infants and children <24 months of age who have received one or more doses of PCV7 should complete the immunization series with PCV13.

Children ≥24 months of age

- A single dose of PCV13 is recommended for all healthy children 24 through 59 months of age with any incomplete PCV schedule (PCV7 or PCV13).
- For children 24 through 71 months of age with underlying medical conditions who have received any incomplete schedule of <3 doses of PCV (PCV7 or PCV13), 2 doses of PCV13 are recommended. For children with underlying medical conditions who have received 3 doses of PCV (PCV7 or PCV13), a single dose of PCV13 is recommended through 71 months of age.
- The minimum interval between doses is 8 weeks.

3. Children completely vaccinated with PCV7

- A single supplemental dose of PCV13 is recommended for all 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).
- For children who have underlying medical conditions, a single supplemental PCV13 dose is recommended through 71 months of age. This includes children who have previously received the 23-valent pneumococcal polysaccharide vaccine (PPSV23).
- PCV13 should be given at least 8 weeks after the last dose of PCV7 or PPSV23.

4. Children 6 through 18 years of age with high risk conditions

- A single dose of PCV13 may be administered to 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, cochlear implant or cerebrospinal fluid leaks, regardless of whether they have previously received PCV7 or PPSV23.

5. Use of PPSV23 among children 2 through 18 years of age who are at increased risk for invasive pneumococcal disease

- In addition to receiving PCV13, children with underlying medical conditions should receive PPSV23 at age 2 years or as soon as possible after the diagnosis of chronic illness is made in children ≥2 years.
- Doses of PCV13 should be completed before PPSV23 is given.
- The minimum interval is at least 8 weeks after the last dose of PCV13. However, children who have previously received PPSV23 should also receive the recommended PCV13 doses.
- A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for children who have sickle cell disease, or functional or anatomic asplenia, HIV-infection, or other immunocompromising condition.
- No more than two PPSV23 doses are recommended.

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During this transition if only PCV7 is available in the clinic unvaccinated and incompletely vaccinated children should receive PCV7. These children should complete the series with PCV13 at subsequent visits. When PCV13 is available in the clinic, unvaccinated and incompletely vaccinated children should receive PCV13 (not PCV7). Active recall is not recommended for children for whom the supplemental PCV13 dose is recommended. The supplemental dose should be given at a subsequent visit.

Recommended Dosage

The recommended dose is 0.5 mL suspension for intramuscular, supplied in a single-dose pre-filled syringe. Refer to package insert at the following link:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

Vaccine Storage and Handling

- Store refrigerated at 2 - 8° C, 35 - 46° F.
- Do not freeze.

Precautions

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including Prevnar 13, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination.

Contraindications

Severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 13, Prevnar (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) or any diphtheria toxoid containing vaccine.

IDPH / Immunization Program Recommendations

IDPH Immunization Program routinely follows and promotes the Recommended Immunization Schedule and will implement the PCV13 vaccine in accordance with the ACIP recommendations.

Vaccine Licensure / VFC Implementation

The Advisory Committee on Immunization Practices (ACIP) provides advice and guidance regarding the most appropriate application of vaccines for effective vaccine preventable disease control. The FDA is responsible for the licensure of vaccines. Upon FDA approval the ACIP convenes and makes decisions on vaccine recommendations. A VFC resolution vote is required for the inclusion of new vaccines into the VFC Program or the modification of existing resolutions. The Centers for Disease Control and Prevention (CDC) then negotiates a contract for the purchase of vaccines. VFC vaccine must be administered according to the guidelines outlined by the ACIP recommendations and VFC resolutions.

CDC allocates individual state VFC funding based upon eligible populations, anticipated vaccine uptake, and negotiated federal contract amounts. CDC establishes monthly vaccine allocations for each vaccine. Additional 317 CDC discretionary funds are used to vaccinate underinsured individuals seen at Local Public Health Agencies (LPHAs) who are not eligible under VFC guidelines. Each state determines the vaccine implementation date based upon the above process which is generally four to six months following vaccine licensure.