



Implementation Guidance - PCV-13 Updated 11-9-11

The American Academy of Pediatrics has developed the following implementation guidance in response to the recent Food and Drug Administration (FDA) licensure. Recommendations for use of PCV -13 have been published in the Morbidity and Mortality Weekly Report (MMWR) and *Pediatrics*. This document is designed to assist practices in the transition from using PCV 7 to PCV 13 vaccines and it will be updated as new policy and implementation information becomes available. Please see the following sections for more information:

- **Policy**
- **Supply**
- **Liability and Risk Communication**
- **Risk Management**
- **Payment**
- **Coding**
- **Patient Education**
- **Additional Resources**

Policy

On March 12, 2010 the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP) published recommendations on the use of a 13-valent pneumococcal conjugate vaccine (PCV13 [Prenvar 13, Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.]). PCV-13 was licensed by the Food and Drug Administration (FDA) for prevention of invasive pneumococcal disease (IPD) caused by the 13 pneumococcal serotypes covered by the vaccine and for prevention of otitis media caused by serotypes in the 7 valent pneumococcal conjugate vaccine formulation (PCV7[Prenvar, Wyeth]). The ACIP recommendations approved by ACIP on February 24, 2010 address the following: 1.) routine vaccination of all children aged 2- 59 months with PCV-13, 2.) vaccination of children aged 60-71 months with underlying medical conditions that increase their risk for pneumococcal disease or complications, and 3) PCV13 vaccination of children who previously received 1 or more doses of PCV 7. Additionally, the MMWR includes guidance for vaccination providers transitioning from PCV7 to the PCV 13 immunization schedule.

- **Full Report:** [Licensure of a 13 – Valent Pneumococcal Conjugate Vaccine \(PCV13\) and Recommendations for Use Among Children --- Advisory Committee on Immunization Practices \(ACIP\), March 12, 2010; 59 \(09\); 258-261](#)

The **American Academy of Pediatrics' updated recommendations on PCV 13** published in *Pediatrics* can be found at the following link: <http://pediatrics.aappublications.org/cgi/content/abstract/peds.2010-1280v1>. Additional information on pneumococcal disease - clinical manifestations, etiology, epidemiology, diagnostics, treatment, and control measures - can be found in the **Red Book 2009** pgs 524 -535 and on [Red Book Online](#) (subscription required).

AAP News: Ensure eligible patients have received supplemental dose of PCV13 (November 2011)
<http://aapnews.aappublications.org/content/32/11/10.1.full.pdf+html>

Supply and Ordering

Supply of PCV-13 vaccine has been adequate to cover a 4-dose series for infants and catch-up of 2-5 year olds in the United States. For continued ordering, consider adding an appropriate number of vaccines to cover 1 catch-up dose for any 2-5 year old in the practice who has not yet received the catch-up dose.

For Prenvar 7, Pfizer has amended its return policy to accept partial package returns for credit as well as waive its policy of only accepting returns within 6 months of the lot's expiration date. As a result, practices can return private inventory of Prenvar 7. Pfizer will not accept returns of Prenvar supplied through the VFC Program

or from any government agency. Prevnar 7 is no longer in production, cannot be ordered, and should not be administered.

The price of Prevnar 13 increased in February 2011 and again in November 2011. The current price is \$120.95 plus a \$0.75 excise tax. Pfizer has extended a pricing promotion for a few months to give time for payers to update their systems with the price increase.

For VFC, Pfizer began shipping Prevnar 13 (and not Prevnar 7) when the contract with VFC was finalized in May 2010. Contact your state VFC contact for details on returning Prevnar 7 and estimated shipment dates for Prevnar 13.

Private catalogue price is \$120.95 per dose plus \$0.75 excise tax. As the only maker of this vaccine, no discounts are known to exist. For other vaccines, a list of group purchasing organizations with which pediatricians report working is available at [Practice Management Online](#). (AAP member log-in required)

Liability and Risk Communication

Vaccine Injury Compensation Program (VICP)

The 13-valent pneumococcal conjugate (PCV13) vaccine is covered by the VICP. Pediatricians should follow the good risk communication and documentation steps for the 13-valent pneumococcal conjugate (PCV13) vaccine as is required for all vaccines covered by the VICP.

An easy way to remember them is to follow the 4 **D**'s.

- **D**istribute the Vaccine Information Statements (VIS) with each dose of the 13-valent pneumococcal conjugate (PCV13) vaccine. A new PCV13 VIS is now available and replaces the VIS for PCV7. It can be downloaded at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-pcv.pdf>
- **D**iscuss the risks and benefits of the vaccine.
- **D**ocument in each patient's permanent medical record that 1) the VIS was provided at the time of vaccination 2) the edition date of each VIS, 3) the name, address, and title of the individual administering a vaccine; 4) the date of vaccine administration; and 5) the vaccine manufacturer and lot number of the vaccine used. Be sure that your documentation is changed to reflect that you have administered the PCV-13 vaccine. This may require updates to the Vaccine Administration Record, EMR records, and state immunization registries.
- **D**ialogue with vaccine doubters. When parents refuse immunization, it's important to try to understand their reasoning and maintain a supportive relationship. Risk managers recommend having parents sign an *informed refusal* document. Here is the link to the AAP refusal form: <http://www.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf>
- The VICP website has an excellent frequently asked question feature. For more information, visit: <http://www.hrsa.gov/vaccinecompensation/>.

A VIS is available for PPSV 23 at <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf>

Although this particular vaccine is not covered by the VICP, it would be good risk communication to distribute and discuss the VIS when offering that vaccine. It would also be good risk management to follow the same documentation practices described above.

Payment

1. Each practice should verify with third party payers if PCV-13 vaccine is a covered benefit and how it will be paid. Third party payers include commercial insurers, Medicaid fee for service and Medicaid Managed care. Generally, for those payers in which vaccines are a covered benefit, most third party payers will base coverage for vaccines on published recommendations by either:
 - ACIP recommendations approved by the CDC as published in the MMWR
 - AAP as published in Pediatrics or the AAP RedBook

Until recommendations are published, those health plan claims systems do not recognize the vaccine as a covered benefit.

2. The AAP will be notifying the major national health plan carriers of the recommendations for the PCV 13 vaccine and urge timely benefits coverage and appropriate payment for the vaccine and immunization administration. Chapters may also consider contacting carriers as well.

3. Each contract with third party payers should be reviewed for provisions for mid-contract inclusions. Make sure the contract includes a clause allowing for mid-contract inclusion of new recommendations with regard to immunizations. Otherwise, you will need to verify with the carriers how they will incorporate new immunization recommendations into the benefits coverage.

4. Contracts should be reviewed regarding payment levels for vaccines. Make sure there is a provision in the fee schedule that allows for payment to be in an amount equal to the **sum** of both the cost of the vaccine and related practice expenses. If health plan payment is set at a level of average wholesale price (AWP) or average sales price (ASP), pediatricians need to identify the source of the AWP or ASP as there are several vendors providing these figures. The AAP supports use of the CDC Vaccine Private Sector price list as the basis for the vaccine cost. This lists the current manufacturer's vaccine price and can be accessed at: <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>

Include a provision in the contract for the health plan to pay not less than the actual invoice plus related practice expense costs. Sample contract language on vaccines is available on the [AAP Member Center](#) and link to Private Payer Advocacy to access the *Vaccine Addendum to Payer Contracts* (<http://www.aap.org/securemoc/reimburse/VaccineAddendumtoPayerContracts.pdf>)

In addition to the payment for the vaccine and related expenses, make sure there is payment for the immunization administration, which is a separate expense. For information on the total direct and indirect costs of immunizations, see the *AAP Business Case for Pricing Vaccines and Immunization Administration on the AAP Member Center* at: (<http://www.aap.org/securemoc/reimburse/BusinessCase.pdf>)

5. Check with your state regarding inclusion of the PCV 13 vaccine in the Vaccines for Children (VFC) program. The VFC program provides the vaccine product at no cost to the practice. Physician practices may charge an administration fee. VFC is not an option for those children having private health insurance benefits available for immunizations. This program is for children aged birth through 18 years who:

- Are eligible for Medicaid
- Have no health insurance
- Are Native American or Alaska Native, or
- Have health insurance, but it does not cover immunizations AND they go to a Federally Qualified Health Center

6. AAP chapters may wish to follow-up with Medicaid and SCHIP programs, to ensure coverage of both the vaccine and its administration. Children eligible for Medicaid should receive the vaccine through the VFC program

7. Practices need to develop payment arrangements with families if coverage is not available through a third party payer. Practices should consider having families sign waivers or advance beneficiary notices (ABN) clarifying financial responsibility for uncovered services under the health plan. Additional information on waivers can be found on the [AAP Member Center](#) and click on the Private Payer Advocacy link to access *Waivers: The Basics for a Pediatric Office*. (<http://www.aap.org/securemoc/reimburse/waivers2006.pdf>)

8. Additional information on immunization financing can be found at <http://www.aap.org/immunization/pediatricians/financing.html>

Coding

The Current Procedural Terminology (CPT) code for the Prevnar 13 vaccine serum is 90670 (*Pneumococcal conjugate vaccine, 13 valent, for intramuscular use*). An appropriate vaccine administration code (90460 or 90471-90472) should also be reported in addition to the serum code. The International Classification of Diseases – 9th Revision – Clinical Modification (ICD-9-CM) code that would be reported with this vaccine is V03.82 (*Need for prophylactic vaccination against Streptococcus pneumoniae [pneumococcus]*). The Prevnar-13 is a single component vaccine.

Patient Education

Articles for parents about pneumococcal are available on AAP's parenting Web site HealthyChildren.org. In addition, a revised patient handout will be posted to [Patient Education Online](#) — AAP's online subscription resource for health care professionals.

Additional Resources

- PCV13 Vaccine Information Statement is available at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>
- Details about the routine pneumococcal conjugate vaccination schedule are available at <http://www.cdc.gov/vaccines/recs/schedules/default.htm#child>
- Adverse events after receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System at <http://vaers.hhs.gov>