



From the Texas Department of State Health Services Immunization Branch

The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.

To view past issues, go to: www.dshs.state.tx.us/immunize/vacadvise/

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The New 13-Valent Pneumococcal Conjugate Vaccine (PCV13)

On February 24, 2010 the U.S. Food and Drug Administration (FDA) approved PCV13 for the prevention of invasive pneumococcal disease and otitis media. On the same day the Advisory Committee on Immunization Practices (ACIP) approved recommendations for use of the new PCV13 vaccine among infants and children.

This advisory summarizes recommendations approved by the ACIP for use of PCV13.

This advisory contains:

1. Background information
2. Summary of ACIP's recommendations for PCV13 vaccine
3. Texas Vaccines for Children program
4. ImmTrac
5. Texas school and child-care facilities requirements for PCV13 vaccine
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1) Background

The ACIP voted on February 24, 2010 to recommend the use of PCV13, which provides broader protection for young children against pneumococcal disease. The ACIP approved the vaccine for active immunization of infants and children 2 through 71 months of age against

Streptococcus pneumoniae-caused invasive pneumococcal diseases, such as pneumonia and meningitis, and against otitis media.

PCV13, manufactured by Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc., succeeds the earlier *Prevnar*, a 7-valent PCV (PCV7). PCV13 protects against 6 more serotypes of *S. pneumoniae* than the original vaccine.

The new PCV13 vaccine is intended to replace the current PCV7 vaccine.

2) Summary of ACIP Recommendations

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.

The recommended schedule for PCV13 is as follows:

- **Unvaccinated infants and children:** PCV13 is recommended for all children 2 through 59 months of age. The dosing schedule is the same as the previously published schedule for PCV7. PCV13 is recommended as a 4-dose series at ages 2, 4, 6, and 12-15 months. Older children will follow the schedule currently recommended for PCV7.
- **Children incompletely vaccinated with PCV7:** Children aged 2 to 59 months who received 1 or more doses of PCV7 should complete their vaccine series with PCV13. The age may be extended to 71 months for children with an underlying medical condition, such as sickle cell disease, HIV, or asplenia.
- **Children completely vaccinated with PCV7:** Those children 14 to 59 months of age who have received all 4 doses of PCV7 should receive a single supplemental dose of PCV13. The age may be extended to 71 months for children with an underlying medical condition.
- **High-risk children aged 6 years and older:** 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 the 23-valent pneumococcal polysaccharide vaccine (PPSV23).
- **Additional vaccine for children with underlying medical conditions:** Children aged 2 years and older who are at increased risk for invasive pneumococcal disease should receive a 23-valent pneumococcal polysaccharide vaccine after vaccination with PCV13.

To access the complete recommendations go to:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm>.

3) Texas Vaccines for Children (TVFC) program

The Centers for Disease Control and Prevention (CDC) has replaced PCV7 with PCV13 for the Vaccines for Children program (VFC), and has updated the VFC resolution to reflect the new recommendations.

For complete information about the updated VFC resolution and the PCV13 vaccine schedule and dosage intervals, go online to:

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

PCV7 Vaccine Return

Unused PCV7 may be returned to McKesson after adequate doses of PCV13 are received.

Please use the following steps for the return of PCV7:

- 1) If possible, CDC has requested that providers return PCV7 by early May.
- 2) As with all TVFC vaccine returns, providers should contact their Health Service Region (HSR) or Local Health Department (LHD) representative for return labels.
- 3) Providers should include the Texas Vaccine Loss Report (C-69) in the container with the vaccine, but do not need to forward copies of this form to LHDs or HSRs as with actual vaccine losses.
- 4) These doses do not need to be shipped as viable vaccine; in other words, no ice packs or other temperature protocols are necessary. Vaccines should be securely packed to prevent breakage.
- 5) Providers should send only State supplied vaccine back to McKesson. Privately purchased PCV7 should be returned back to Pfizer.

The following chart indicates PCV7 vaccine lots distributed to TVFC providers within the past year:

VACCINE	LOT	EXP. DATE		VACCINE	LOT	EXP. DATE
PNU 7	C27701	31-Mar-11		PNU 7	D50002	28-Feb-11
PNU 7	C27703	31-Mar-11		PNU 7	D50003	30-Nov-11
PNU 7	C57963	31-Mar-11		PNU 7	D59297	30-Nov-11
PNU 7	C99082	28-Feb-11		PNU 7	D61921	30-Nov-11
PNU 7	D05879	23-Apr-09		PNU 7	D65510	31-Jan-12
PNU 7	D16280	31-May-11		PNU 7	D66586	31-Jan-12
PNU 7	D16282	28-Jun-11		PNU 7	D66591	31-Jan-12
PNU 7	D18702	31-Jul-11		PNU 7	D74804	29-Feb-12
PNU 7	D21051	28-Jul-11		PNU 7	D75884	24-Dec-09
PNU 7	D22943	30-Jul-11		PNU 7	D75885	29-Feb-12
PNU 7	D23075	31-Jul-11		PNU 7	D78697	29-Feb-12
PNU 7	D24322	31-Jul-11		PNU 7	D81704	29-Feb-12
PNU 7	D33501	30-Sep-11		PNU 7	D84740	31-Mar-12
PNU 7	D34438	31-Aug-11		PNU 7	D84741	31-Mar-12
PNU 7	D36145	30-Sep-11		PNU 7	D88183	31-Mar-12
PNU 7	D36147	30-Sep-11		PNU 7	D90887	30-Apr-12
PNU 7	D37015	30-Sep-11		PNU 7	D93210	30-Apr-12
PNU 7	D37052	30-Sep-11		PNU 7	D93211	30-Apr-12
PNU 7	D39015	30-Sep-11		PNU 7	D94433	30-Apr-12
PNU 7	D39210	30-Apr-12		PNU 7	D94434	30-Apr-12
PNU 7	D46875	31-Oct-11		PNU 7	E07298	30-Sep-13
PNU 7	D48927	31-Oct-11		PNU 7	E13862	30-Sep-13
PNU 7	D48928	31-Oct-11		PNU 7	E15305	30-Sep-13

The CPT code for PCV13 is 90670.

For questions about PCV13 or the PCV7 return process, please contact your local health department or health service region.

4) ImmTrac

ImmTrac users may use the code “Pneumococcal (PCV13)” or CPT code 90670 to report administration of the PCV13 vaccine. The doses will be reflected on the client’s vaccination history.

The ImmTrac immunization scheduler will generate recommendations for the next PCV13 vaccine and will no longer recommend doses of PCV7.

Providers should consult ACIP recommendations to determine when the PCV13 vaccine should be administered.

For more information about ImmTrac, visit www.ImmTrac.com.

5) Texas school and child-care facilities requirement for pneumococcal vaccine

Pneumococcal vaccine is required for students attending child-care facilities in Texas. Children may receive either PCV7 or PCV13, or a combination of these two to be considered in compliance. The number of doses required depends on the age of the child when the first dose was administered.

A summary chart of the Texas Minimum State Vaccine Requirements for child-care facilities is currently found at http://www.dshs.state.tx.us/immunize/docs/school/6-15_2010-2011.pdf. This chart summarizes the vaccine requirements incorporated in Title 25 Health Services, §97.61-97.72 of the Texas Administrative Code (TAC).

6) Epidemiology and surveillance

Summa *Streptococcus pneumoniae*, also called pneumococcus, causes a range of illnesses, depending on the site of infection (e.g., acute otitis media, pneumonia, bacteremia, or meningitis). The case fatality rate varies by type of infection: 5-7% for pneumonia, 20% for bacteremia and 30% for meningitis. Case fatality rates are even higher among elderly populations. Carriage of *S. pneumoniae* is common. It can be found in the nasopharynx of 5-70% of healthy adults and 21-59% of children. More than 90 serotypes have been identified though the 10 most common serotypes account for 62% of invasive disease world wide.

The first pneumococcal polysaccharide (PS) vaccine, licensed in 1977, was effective against 14 of the 90 types of *S. pneumoniae*. The PS vaccine used today for older children and adults is effective against 23 types of *S. pneumoniae*. This 23-valent PS vaccine protects against 85% to 90% of the types of the *S. pneumoniae* that cause invasive infections in this age group. Because polysaccharide vaccines are not effective in children younger than two to three years of age, a conjugate vaccine was developed in 2000. The 7-valent conjugate vaccine targeted the seven most common types of the *S. pneumoniae*, which account for 80% of invasive disease in infants and toddlers. The new 13-valent vaccine will target the seven from the 7-valent vaccine plus an additional six serotypes.

Invasive *Streptococcus pneumoniae* infection is a reportable condition in Texas.

7) Reporting adverse vaccine events

An adverse event is a health problem that is reported after someone gets a vaccine or medicine. Adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). While VAERS is an important system for helping to identify

potential vaccine safety issues, VAERS is not able to determine if an adverse event was caused by vaccination.

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. You may also contact VAERS at (800) 822-7967 for forms and information.

In Texas, reports of adverse events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program should be reported through the Texas Department of State Health Services, Immunization Branch via fax or mail.

- Fax a completed VAERS form to: 1-866-624-0180 (toll-free)
- Mail a completed VAERS form to DSHS, Immunization Branch, MC-1946, P.O. Box 149347, Austin, TX 78714-9347

A pre-addressed and postage-paid VAERS form can be obtained by calling the Immunization Branch. A copy of the form is also available in the TVFC Toolkit. For more information about VAERS, you can contact DSHS at 800- 252-9152.

8) Resources

- Food and Drug Administration. Vaccines: approved products. Prevnar 13 (pneumococcal 13-valent conjugate vaccine). Available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm201667.htm>
- CDC. Preventing pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices (ACIP): <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4909a1.htm>
- CDC. Recommended immunization schedule for persons aged 0 through 18 years---United States, 2010: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5851a6.htm>
- Prevnar 13 (PCV13) prescribing information: <http://www.wyeth.com/content/showlabeling.asp?id=501>
- Centers for Disease and Control and Prevention-Vaccine Safety www.cdc.gov/vaccinesafety

We hope you generously forward this advisory to others who may benefit from this information.

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