



DAVID MAXWELL-JOLLY
Director

State of California—Health and Human Services Agency
Department of Health Care Services



ARNOLD SCHWARZENEGGER
Governor

June 10, 2010

CHDP Provider Information Notice No.: 10-03

TO: ALL CHILD HEALTH AND DISABILITY PREVENTION (CHDP)
PROGRAM PROVIDERS AND MEDI-CAL MANAGED CARE PLANS

SUBJECT: PNEUMOCOCCAL CONJUGATE VACCINE (PCV 13/ PREVNAR 13™)
ADDITION AS A CHDP BENEFIT, CODE 88, AND UPDATED CHDP
VACCINE BENEFIT AND REIMBURSEMENT TABLE

The purpose of this Information Notice is to advise you that the heptavalent, pneumococcal conjugate vaccine (PCV 13, brand name Prevnar 13™) has been added as a Child Health and Disability Prevention (CHDP) program benefit (code 88), effective March 1, 2010.

This Information Notice provides background information on the vaccine, the new CHDP administration code, and the provider reimbursement rate for vaccine administration. An updated CHDP vaccine benefit and reimbursement table is enclosed that includes the addition of the Prevnar 13™ vaccine. The VFC provider letter on PCV 13 is also enclosed.

Background Information

Streptococcus pneumoniae (pneumococcus) causes bacteremia, meningitis, pneumonia, sinusitis, otitis media and other illnesses. Prior to licensure of PCV7 which protects against 7 serotypes of pneumococcus, pneumococcal infection was the most common cause of invasive bacterial disease in children older than one month of age. Invasive pneumococcal disease has decreased by 76 percent in children under five since 2000 when PCV7 was released. Infections caused by other pneumococcal serotypes, however, have increased, leading to development of the 13-valent vaccine. Infants and children with immunocompromising conditions, certain other chronic health conditions or cochlear implants are at increased risk of severe pneumococcal disease.

On February 24, 2010, Prevnar 13™, a 13-valent pneumococcal conjugate vaccine (PCV13) was licensed by the Food and Drug Administration 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 [Pevnar, Wyeth]). The ACIP issued recommendations on the same day for vaccination with PCV13 of 1) all children aged 2 - 59 months, 2) children under six years of age who previously received one or more doses of PCV7, and 3) children aged 60 - 71 months with underlying medical conditions that increase their risk for pneumococcal disease or complications.

Recommendations for Use of PCV13 in the CHDP Program

For children who have not received prior PCV7 or PCV13 vaccine:

- Infants two through six months of age: PCV13 is recommended as a four dose series at two, four, six and 12 - 15 months.
 - Recommended interval between the first three doses is eight weeks, with a minimum interval of four weeks.
 - Minimum age for administration is six weeks.
 - Fourth dose should be administered at age 12 - 15 months and at least eight weeks after the third dose.
- Infants and children seven months through 11 months of age: Three doses are recommended. The first two doses should be given with a minimum interval of at least four weeks between the doses. The third dose should be given at age 12 through 15 months and at least eight weeks after the second dose.
- Children 12 through 23 months of age: two doses should be administered with a minimum interval of eight weeks between doses.
- Children 24 months through 59 months with no underlying medical condition: one dose of PCV13 should be administered.
- Children 24 months through 71 months with an underlying medical condition¹: two doses of PCV13 should be administered.

For children incompletely vaccinated with PCV7 or PCV13:

- Children <24 months of age who have received one or more doses of PCV7 should complete the immunization series with PCV13.
- Children 24 through 59 months of age with no underlying medical condition: a single dose of PCV13 is recommended.

¹ See VFC letter for list of underlying conditions that modify the PCV13 vaccination schedule

- Children 24 through 71 months with underlying medical condition who have received:
 - 0 - 2 doses of PCV7 or PCV13: two doses of PCV 13 are recommended.
 - three doses of PCV7 or PCV13: one dose of PCV13 is recommended.

The minimum interval between doses is eight weeks.

For children completely vaccinated with PCV7:

For children 14 through 59 months who are completely vaccinated with PCV7, one dose of PCV13 is recommended. For children with underlying high risk medical conditions (see VFC program letter for more information) who are 24 through 71 months of age and completely vaccinated with PCV7, one dose of PCV13 is recommended.

Further information on PCV13 use for the above groups as well as for children six through 18 years of age with underlying medical conditions who are eligible to receive PCV13 under the VFC program can be found in the VFC letter and MMWR:

<http://www.eziz.org/PDF/13ValentPneumococcalConjugateVac.pdf> (attached) and at <http://www.cdc.gov/mmwr/PDF/wk/mm5909.pdf>.

PCV13 as a CHDP Program Benefit

Effective immediately, CHDP will reimburse providers for the administration fee of Pneumococcal 13-valent conjugate vaccine, PCV13/Prevnar13™, to CHDP eligible infants and children for vaccine given on or after March 1, 2010; the vaccine will be provided at no charge by the VFC Program. The CHDP vaccine code is 88 and has the reimbursement rate of \$9.00 for the administration fee.

PCV13	CHDP Code 88	VFC	6 weeks through 18 years, 11 months	\$9.00	High Risk Factor if older than 4 years, 11 months
-------	-----------------	-----	--	--------	---

Code 88 is payable for up to four doses when administered according to the schedule outlined above and in the VFC Provider letter. PCV13 has been added to the Vaccine Codes and Rates Table found in the rates max section of the CHDP Provider Manual.

Reminder: All CHDP program providers actively involved with vaccination of children must participate in the VFC Program, which provides vaccines at no cost to the provider for eligible children through eighteen years, eleven months. The CHDP Program reimburses only the immunization administration fee for VFC covered services.

Billing Instructions for Prevnar13™ vaccine

Please use the following instructions when billing for administration of PCV13. Refer to the CHDP Provider Manual for additional information.

Enter the CHDP Code number 88, and PCV13 on a blank line under the immunization section of the PM160 Confidential Screening/Billing Report.

Enter a check mark in only one of the Immunization Outcome Columns (A or B) of the PM160 as appropriate.

Enter the administration fee in the Fees Column (Note: fees to not apply on the "Information Only" PM160).

Enter the comment "High Risk Factor" for children older than four years, 11 months.

There is no comment required for children six weeks through four years, 11 months.

If you have administered PCV13 on or after March 1, 2010 and prior to this notice, you are entitled to reimbursement for the purchase of this vaccine if you have not been previously reimbursed for the vaccine by any source. Please submit a PM160 for the \$9.00 administration fee for each dose administered.

CHDP Vaccine Benefits and Reimbursement Table

An updated CHDP Vaccine Benefit and Reimbursement Table are enclosed. The table includes PCV13 vaccine codes and reimbursement rates. Your continuing participation in the CHDP Program is greatly appreciated. If you have any questions about CHDP vaccine benefits or other CHDP issues, please contact your local CHDP Program office.

Original Signed by Harvey Fry for Luis R. Rico

Luis R. Rico, Acting Chief
Children's Medical Services Branch

Enclosures

**CHDP Vaccine Codes and Rates
June 10, 2010**

Vaccine	Code	Vaccine Source	Age	Rate ¹	Comment Required
DTaP	45	Vaccines For Children (VFC)	2 months thru 6 years, 11 months	\$ 9.00	
DTaP-Hib-IPV	82	VFC	2 months thru 4 years, 11 months	\$ 9.00	
DTaP-IPV	83	VFC	4 years thru 6 years, 11 months	\$ 9.00	
DT Pediatric	59	Purchased	2 months thru 6 years, 11 months	\$ 10.93	
Td Adult	60	Purchased	7 years thru 20 years, 11 months	\$ 13.96	
Td Adult PF	58	VFC	7 years thru 18 years, 11 months	\$ 9.00	
Tdap	72	VFC	10 years thru 18 years, 11 months	\$ 9.00	
	79	Purchased	19 years thru 20 years, 11 months	\$ 45.79	Use this code for one dose
Hepatitis A	65	VFC (Pediatric)	1 year thru 18 years, 11 months	\$ 9.00	
	66	Purchased (Adult)	19 years thru 20 years, 11 months	\$ 70.28	
HBIG ²	41+57	Purchased	Birth thru 20 years, 11 months	\$ 168.12	Reason for administration
Hepatitis B/Hib Combination	56	VFC	2 months thru 4 years, 11 months	\$ 9.00	
Hepatitis B Lower Dose (Pediatric/Adolescent)	40	VFC	Birth thru 18 years, 11 months	\$ 9.00	
Hepatitis B Higher Dose (Adult)	42	VFC	11 years thru 15 years, 11 months ³	\$ 9.00	Use this code for two dose adolescent schedule
Hepatitis B	51	Purchased	19 years thru 20 years, 11 months	\$ 67.98	

1. Total reimbursement, includes administration fee.
2. Only for infants with HBsAg (+) mothers and for children exposed to known/suspected HBsAg (+) blood/tissue fluids.
3. Adolescent two-dose immunization schedule, currently approved for ages 11 years thru 15 years, 11 months.

**CHDP Vaccine Codes and Rates
(Continued – [6/10/10])**

Vaccine	Code	Vaccine Source	Age	Rate ¹	Comment Required
Hib	38	VFC	2 months thru 18 years, 11 months	\$ 9.00	High risk factor, if older than 5 years
	63	Purchased	19 years thru 20 years, 11 months	\$ 25.00	High risk factor
Human Papillomavirus (HPV)	76	VFC	9 years thru 18 years, 11 months	\$ 9.00	
	77+78 ⁴	Purchased	19 years thru 20 years, 11 months	\$ 146.96	
<u>Bivalent Human Papillomavirus (HPV2)</u>	<u>85⁴</u>	<u>VFC</u>	<u>9 years thru 18 years, 11 months</u>	<u>\$ 9.00</u>	
	86+87 ⁴	Purchased	19 years thru 20 years, 11 months	\$ 150.38	
Influenza ⁵ (Inactivated)	53	VFC	6 months thru 18 years, 11 months	\$ 9.00	
	54	Purchased	36 months thru 20 years, 11 months	\$ 13.76	
Influenza ⁵ (Inactivated) Preservative-Free FluMist ⁵	80	Purchased	6 months thru 35 months	\$ 18.71	
	71	VFC	2 years thru 18 years, 11 months	\$ 9.00	
Influenza A (H1N1)	84	Non-VFC	6 months thru 20 years, 11 months	\$ 9.00	
MMR	33	VFC	12 months thru 18 years, 11 months	\$ 9.00	
	48	Purchased	19 years thru 20 years, 11 months	\$ 59.19	
MMRV	74	VFC	12 months thru 18 years, 11 months	\$ 9.00	
Measles ⁶	34	Purchased	12 months thru 20 years, 11 months ⁷	\$ 21.29	Reason for administration
Meningococcal Conjugate Vaccine (MCV4)	69	VFC	2 years thru 18 years, 11 months	\$ 9.00	High risk factor if younger than 11 years
	70+73	Non-VFC Purchased	19 years thru 20 years, 11 months	\$ 101.84	
Pediarix™	68	VFC	2 months thru 6 years, 11 months	\$ 9.00	
Polio - Inactivated	39	VFC	2 months thru 18 years, 11 months	\$ 9.00	
	64	Purchased	19 years thru 20 years, 11 months	\$ 59.59	

1. Total reimbursement, includes administration fee.
4. For females only
5. For one dose annually, except for children 2 years thru 8 years, 11 months who have never received an influenza immunization. These children should receive two doses, with an interval of 28 days.
6. For individuals with a contraindication to rubella or mumps vaccine.
7. Measles vaccine (or if not available, MMR vaccine) is recommended in children as young as 6 months in outbreak situations, or for international travel.

**CHDP Vaccine Codes and Rates
(Continued – [6/10/10])**

Vaccine	Code	Vaccine Source	Age	Rate ¹	Comment Required
Pneumococcal Polysaccharide (23PS)	55	Purchased	2 years thru 20 years, 11 months	\$ 56.69	High risk factor
Pneumococcal Heptavalent (Pevnar)	67	VFC	1 month thru 4 years, 11 months	\$ 9.00	
Pneumococcal 13 - valent (Pevnar 13)	88	VFC	6 weeks thru 18 years, 11 months	\$ 9.00	High risk factor if older than 4 years 11 months
Rotavirus ⁸ (Rotateq™)	75	VFC	6 weeks thru 32 weeks	\$ 9.00	
Rotavirus ⁹ (Rotarix™)	81	VFC	6 weeks thru 32 weeks	\$ 9.00	
Rubella ¹⁰	36	Purchased	12 months thru 20 years, 11 months	\$ 24.50	Reason for administration
Varicella	46	VFC	12 months thru 18 years, 11 months	\$ 9.00	
	52	Purchased	19 years thru 20 years, 11 months	\$ 99.03	

1. Total reimbursement, includes administration fee.
8. Oral vaccine, 3 doses (Rotateq™).
9. Oral vaccine, 2 doses (Rotarix™), recommended dosing 2 months and 4 months with completion by 24 weeks.
10. For individuals with a contraindication to measles or mumps vaccine.



State of California—Health and Human Services Agency
California Department of Public Health



MARK B HORTON, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

March 23, 2010

IZB-FY0910-7

TO: California Vaccines for Children (VFC) Program Providers
FROM: John Talarico, D.O., M.P.H., Chief *J. Talarico, D.O.*
Center for Infectious Diseases
Division of Communicable Disease Control, Immunization Branch
SUBJECT: 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE [DIPHTHERIA CRM₁₉₃
PROTEIN] (PCV13) IS NOW AVAILABLE FROM VFC TO REPLACE PCV7

Section	Page
Summary	1
Background	2
Composition	2
Recommendations for Vaccine Use	3
Eligible Groups	3
PCV-13 Vaccine Recommendations	3
Administration of PCV-13 Vaccine	6
Administration with other vaccines	6
How Supplied	6
Potential Vaccine Reactions	6
Contraindications	6
Precautions	6
Ordering and Billing	6
Documentation	8

SUMMARY

On February 24, 2010, the United States [Food and Drug Administration \(FDA\)](#) licensed a [13-valent pneumococcal conjugate vaccine \(PCV13\), Prevnar 13™](#), for the prevention of invasive disease and otitis media in children 6 weeks through 5 years (71 months) of age. PCV13 replaces the 7-valent pneumococcal conjugate vaccine (PCV7), Prevnar™. The [federal Advisory Committee on Immunization Practices \(ACIP\)](#) now recommends the routine use of [PCV13](#) as a four-dose series at 2, 4, 6, and 12-15 months. [PCV13 is now available from VFC](#) for all VFC-eligible children 6 weeks through 5 years of age and for those with high risk conditions through age 18 years. The California Department of Public Health, Immunization Branch is following ACIP's recommendations for use of pneumococcal vaccines.

BACKGROUND

Streptococcus pneumoniae (pneumococcus) causes bacteremia, meningitis, pneumonia, empyema and other severe illnesses. It is also a cause of otitis media, sinusitis, and conjunctivitis. Prior to the licensure of PCV7 in 2000, *S. pneumoniae* was the most common cause of invasive bacterial disease in children older than one month of age. PCV7 protects against pneumococcal serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F. Since the introduction of PCV7, invasive pneumococcal disease among children younger than age five years in the U.S. has decreased by 76%. Invasive pneumococcal disease has also decreased in adults, presumably through decreased transmission and carriage after immunization of children with PCV7.

However, infections caused by additional pneumococcal serotypes have subsequently increased. Pneumococcal serotype 19A is currently the most common cause of invasive bacterial disease in children. PCV13 also protects against serotypes 1, 3, 5, 6A, 7F, and 19A, which in one US study have been associated with 64% of recent cases of invasive pneumococcal disease of known serotype in children younger than 5 years.

Pneumococcal infections are most common in infants, young children, elderly persons, and black, Alaska Native, and some American Indian populations. In addition, those with congenital or acquired humoral immunodeficiency, human immunodeficiency virus (HIV) infection, absent or deficient splenic function (e.g., sickle cell disease, functional or anatomic asplenia), other immunocompromising conditions, and certain chronic health conditions are at higher risk of pneumococcal infection or more severe disease. Children with cochlear implants have high rates of pneumococcal meningitis.

COMPOSITION

PCV13 is a sterile suspension of saccharides of the capsular antigens of the 13 pneumococcal serotypes individually conjugated to CRM₁₉₇ protein, a nontoxic variant of diphtheria toxin isolated from cultures of *C. diphtheriae* strain C7 (β 197) grown in casamino acids and yeast extract-based medium. The polysaccharides of the capsular antigens of the 13 serotypes included in the vaccine are purified and chemically activated to make saccharides, which are then conjugated to the protein carrier CRM₁₉₇ to form the glycoconjugates. The individual glycoconjugates are purified and compounded to formulate the vaccine.

Each 0.5mL dose of PCV13 is formulated to contain approximately 2.2 mcg of each of the *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F saccharides, 4.4 mcg of 6B saccharides, and 34 mcg CRM₁₉₇ carrier protein. The vaccine also contains 125 mcg aluminum as aluminum phosphate adjuvant.

The tip cap and rubber plunger of the pre-filled syringe do not contain latex. The vaccine contains no thimerosal preservative.

Immunogenicity was compared between PCV13 and PCV7. In recipients of PCV13 pneumococcal anti-capsular polysaccharide IgG antibody concentrations were non-inferior for 10 of 13 serotypes after 3 doses (exceptions, serotypes 6B, 9V, and 3) and 12 of 13 serotypes after 4 doses (exception, serotype 3) Opsonophagocytosis assay (OPA) antibodies were comparable between recipients of PCV13 and PCV7 for all serotypes. [See product insert](#) for more details.

RECOMMENDATIONS FOR PCV13 VACCINE USE IN THE VFC PROGRAM

Children Eligible for VFC Supplies of PCV13

Children eligible for PCV 13 under VFC include ages

- 6 weeks through 59 months regardless of underlying conditions
- 60 through 71 months of age with conditions that increase their risk of pneumococcal disease or its complications (see below)
- 6 through 18 years with sickle cell disease, HIV infection or other immunocompromising conditions, cochlear implants, or CSF leaks.

ACIP and CDPH Recommendations for PCV13

ACIP and CDPH recommend PCV13 for

- all children 2 through 59 months of age and
- children 60 through 71 months of age with certain underlying medical conditions that increase their risk of pneumococcal disease or its complications, including:
 - Chronic heart disease, particularly cyanotic congenital heart disease and cardiac failure
 - Chronic lung disease, including asthma if on prolonged high-dose oral corticosteroids
 - Diabetes mellitus
 - Cerebrospinal fluid leaks
 - Cochlear implant
 - Children with functional or anatomic asplenia
 - Sickle cell disease and other hemoglobinopathies
 - Congenital or acquired asplenia, or splenic dysfunction
 - Children with immunocompromising conditions
 - HIV infection
 - Chronic renal failure and nephrotic syndrome
 - Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation
 - Congenital immunodeficiency, including B- or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency, and phagocytic disorders (excluding chronic granulomatous disease).

1. Routine schedule for children who have not previously received PCV7 or PCV13

The [recommended immunization schedules for children 2 through 59 months of age who have not received any prior PCV7 or PCV13 doses are unchanged from those previously published for PCV7](#), except that PCV13 now replaces 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--15 months, similar to PCV7. Infants receiving their first dose when younger than 6 months should receive 3 doses of PCV13 at intervals of approximately 8 weeks (the minimum interval is 4 weeks). The minimum age for administration of first dose is 6 weeks. The fourth dose is recommended at age 12--15 months and should be given at least 8 weeks after the third dose (Table 1).
- **Unvaccinated children at least 7 months of age**
For previously unvaccinated children 7 months of age and older, please see Table 1.

2. Children incompletely vaccinated with PCV7 or PCV13

- **Children <24 months of age**
who have received one or more doses of PCV7 should complete the immunization series with PCV13 (Table 2).
- **Children at least 24 months of age**
For all healthy children 24 through 59 months of age with an incomplete PCV7 or PCV13 schedule, a single dose of PCV13 is recommended, [similar to prior recommendations for PCV 7](#).

For children 24 through 71 months of age with underlying medical conditions who have received:

- 0-2 doses of PCV7 or PCV13: 2 doses of PCV13 are recommended.
- 3 doses of PCV7 or PCV13: 1 dose of PCV13 is recommended

The minimum interval between doses is 8 weeks.

3. Children completely vaccinated with PCV7 - give 1 more dose of PCV13

For all healthy children 14 through 59 months of age who are completely vaccinated with PCV7, a single supplemental dose of PCV13 is recommended (Table 2).

For all children with underlying medical conditions who are 14 through 71 months of age and completely vaccinated with PCV7, a single supplemental dose of PCV13 is recommended (Table 2). This includes children who have previously received the 23-valent pneumococcal polysaccharide vaccine (PPSV23).

The minimum interval between doses, including doses of PPSV23, is 8 weeks

For children 6 through 18 years of age with sickle cell disease, HIV-infection or other immunocompromising condition, cochlear implant or cerebrospinal fluid leaks, a single supplemental dose of PCV13 may be administered regardless of prior receipt of PCV7 or PPSV23. Routine use of PCV13 is not recommended for healthy children ≥ 5 years.

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

Children with underlying medical conditions should also receive PPSV23 at age 2 years or as soon as possible after the diagnosis of chronic illness is made at older ages. 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.

Transition from PCV7 to PCV13 within your Office:

Your office will be replacing PCV7 with PCV13. Please make sure to review the updated ACIP recommendations and to train your entire office staff regarding the implications of this transition for your practice. This transition will affect your vaccine ordering, billing, and documentation.

Please make sure to understand the implications of both catch-up vaccination and vaccination of high-risk patients when placing your orders.

Until doses of PCV13 are received at your practice, PCV7 should be administered to those children and infants who are due for their next PCV dose. Once doses of PCV13 arrive, children should complete their series with PCV13 at their next routine visit (rather than through mass recall) according to the current ACIP recommendations provided in this letter. After receipt of PCV13, any remaining unused doses of PCV7 should be immediately returned to VFC's national distributor by April 30, 2010 (see details under Return of Unused Inventory).

Table 1: Recommended Routine Vaccination Schedule for PCV13 Among Infant and Children who have not Received a Previous dose of PCV7 or PCV13, by Age at First Dose

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

*For children vaccinated at age <12 months, the minimum interval between doses is 4 weeks; otherwise, minimum interval between doses of 8 weeks.

[†]Given at least 8 weeks after the previous dose.

Table 2: Recommended Transition Schedule from PCV7 to PCV13, according to previous PCV7 doses received

Infant Series			Booster Dose	Supplemental PCV13 Dose
2 Months	4 Months	6 Months	≥ 12 Months	14-59 Months
PCV7	PCV13	PCV13	PCV13	-
PCV7	PCV7	PCV13	PCV13	-
PCV7	PCV7	PCV7	PCV13	-
PCV7	PCV7	PCV7	PCV7	PCV13 [‡]

[‡]For children with underlying medical conditions, a single supplemental PCV13 dose is recommended through age 71 months. A supplemental PCV13 dose may also be given for those 6 through 18 years of age for persons with sickle cell disease, HIV-infection or other immunocompromising condition, cochlear implant or cerebrospinal fluid leak.

ADMINISTRATION OF PCV13

The vaccine syringe should be inspected carefully prior to administration; the vaccine should not be administered if the syringe is cracked or if particulate matter or discoloration is noted. Shake the syringe vigorously immediately prior to use to resuspend vaccine. Vaccine should be a homogenous, white suspension after shaking. Do not use vaccine if the product cannot be resuspended.

The 0.5 mL vaccine dose should be administered intramuscularly in the anterolateral aspect of the thigh of infants and the deltoid muscle of toddlers and young children.

Administration of PCV13 with other vaccines

PCV13 vaccine may be given at the same visit when other age appropriate vaccines are provided. Vaccines should be given in separate syringes and different injection sites (at least one inch apart). Do not mix Prevnar 13™ with other vaccines/products in the same syringe.

HOW SUPPLIED FOR CALIFORNIA VFC PROGRAM PROVIDERS

PCV13 is supplied as a package of 10 pre-filled syringes (NDC 0005-1971-02).

Storage

- PCV13 should be refrigerated at 35 - 46 degrees F (2 - 8 degrees C).
- Do not freeze.

POTENTIAL VACCINE REACTIONS

The incidence and severity of solicited local and systemic reactions to PCV13 is comparable with those to PCV7. The most common reports within 7 days after administration of PCV13 were injection-site reactions, fever, decreased appetite, irritability, and increased or decreased sleep.

Providers should report suspected reactions to PCV13 or other vaccines to the Vaccine Adverse Events Reporting System (VAERS) at 800-822-7967 (toll-free) or <http://vaers.hhs.gov>.

CONTRAINDICATIONS

- History of severe allergic reaction (e.g., anaphylaxis) to any component of PCV13, PCV7 or any diphtheria toxoid-containing vaccine (please see [product insert](#) for more details).

PRECAUTIONS

- Pneumococcal conjugate vaccines can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever).
- Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.

ORDERING AND BILLING

How to Order

VFC Providers will be automatically transitioned from the 7-valent pneumococcal conjugate vaccine to the 13-valent pneumococcal conjugate vaccine. All PCV vaccine requests received as of March 18, 2010, are automatically being fulfilled with the new 13-valent pneumococcal conjugate vaccine. VFC Providers should review the [provisional ACIP Recommendations for Use of Pneumococcal Conjugate Vaccines](#) with their staff to transition from PCV7 to PCV13.

There will be no changes to the current version of the VFC Order Form (CDPH 8501 (03/10)). Routine orders for the 13-valent pneumococcal conjugate vaccine may be submitted using the current form. Remember to complete all the boxes in the four columns of the order form and accurately account for all VFC vaccine doses received since with your previous order, plus doses reported on-hand in your previous order. Maintain a copy of your order forms for your office files.

Supplemental Orders

In an effort to reduce existing PCV7 inventories, VFC actively reduced provider requests for this vaccine during the weeks prior to the product transition. If your clinic received a reduced order for PCV7, you may re-submit a supplemental order for PCV13 to last until your next regular order.

Return of Unused Inventory of PCV7

Providers with existing supplies of PCV7 should return unused doses to VFC's national vaccine distributors as soon as requested doses of PCV13 arrive. **Doses must be returned by April 30th, 2010.** The new federal contract price for each 10-dose box of this product is \$917.50. Please ensure your clinic returns any unused doses for significant cost savings to the program.

Unused doses should be returned following the same return procedure for non-viable VFC vaccine returns. A VFC Return/Transfer Form must be included in the vaccine shipment and also faxed to the VFC Program. You may obtain a copy at www.eziz.org. A return label may be requested by contacting the VFC Program's Customer Service Center.

Billing Information for VFC PCV13 Vaccine

Child Health and Disability Prevention Program (CHDP): The CHDP administration fee is \$9.00 using CHDP code 88 for up to 5 doses of the 13-valent pneumococcal conjugate vaccine supplied by VFC administered to children through the age of 18 years enrolled in the CHDP Program.

However, providers should wait until notified by CHDP to submit claims for the 13-valent pneumococcal conjugate vaccine. CHDP Provider Information Notices can be found at <http://www.dhcs.ca.gov/formsandpubs/publications/Pages/CMSLetters.aspx>.

Medi-Cal Fee-For-Service (FFS):

Providers should wait until information is published in the Medi-Cal provider bulletin to submit claims as the specific codes and their implementation date are not final until published in the Medi-Cal provider bulletin (http://files.medi-cal.ca.gov/pubsdoco/Bulletins_menu.asp). Services are not considered benefits of the Medi-Cal Program until published in the Provider Bulletin. Providers should check the Medi-Cal provider manual for final codes and implementation date(s). The provider manual can be downloaded at: http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/vaccine_m00o03o04o11.doc.

Other codes for the use of pneumococcal conjugate vaccine that is not supplied by VFC:

- The CPT code for 13-valent pneumococcal conjugate vaccine is **90670**.
- The ICD-9-CM code for the need for prophylactic vaccination against pneumococcus is **V03.82**.

DOCUMENTATION

- PCV13 Product Insert: contains additional vaccine information:
- Vaccine Information Statement (VIS): <http://www.cdc.gov/vaccines/pubs/vis/default.htm>.
- ACIP recommendations: <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>
- Invasive Pneumococcal Disease in Young Children Before Licensure of 13-Valent Pneumococcal Conjugate Vaccine—United States, 2007.
<http://www.cdc.gov/mmwr/PDF/wk/mm5909.pdf>
- Preventing Pneumococcal Disease Among Infants and Young Children. MMWR 2000: 49(RR-9). <http://www.cdc.gov/mmwr/PDF/rr/rr4909.pdf>
- CDC Provider and Parent Q & A: will be available at www.cdc.gov/vaccines .
- AAP recommendations (members-only): <http://www.cispimmunize.org/>
- VFC resolution No. 02/10-1: The VFC resolution on pneumococcal conjugate vaccines can be found at: <http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm>.
- Vaccine Injury Compensation Program (VICP) covers PCV13 vaccine. Information on the federal VICP and pneumococcal vaccines will be found at: <http://www.hrsa.gov/vaccinecompensation/>.

Enclosures: Order Form (03/10)

cc: CDPH Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Local Health Department CHDP Program Directors
Tanya Homman, Chief, Medi-Cal Managed Care Division, DHCS
Luis Rico., Acting Chief, Children Medical Services Branch, DHCS
Susan McClair, M.D., Acting Chief, Medical Policy, Medi-Cal Managed Care,
DHCS
Shabbir Ahmad, D.V.M., M.S., Ph.D., Acting Chief, Maternal, Child and Adolescent Health
Program, CDPH
Shelley Rouillard, Deputy Director, Benefits and Quality Monitoring Division,
MRMIB
Lilia Coleman, Benefits and Quality Monitoring, MRMIB
Jamie Yang, Benefits and Quality Monitoring, MRMIB
Neal Kohastu, M.D., M.P.H., Medical Policy Section, Medi-Cal Benefits, Waiver
Analysis and Rates Division, DHCS
Steve Shih, M.D. Medical Policy Section, Medi-Cal Benefits, Waiver Analysis and
Rates Division, DHCS
Alan Morita, Pharm.D., Medi-Cal Pharmacy Policy Branch, DHCS
Jill Abramson, M.D., M.P.H., Children Medical Services Branch, DHCS