



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



ARNOLD SCHWARZENEGGER  
*Governor*

September 19, 2008

CHDP Provider Information Notice No.: 08-25

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

SUBJECT: ADDITION OF PENTAVALENT COMBINATION VACCINE  
(PENTACEL™) CODE 82 AS A CHDP BENEFIT AND UPDATED CHDP  
VACCINE BENEFIT AND REIMBURSEMENT TABLE

The purpose of this Provider Information Notice (PIN) is to inform you that the pentavalent combination vaccine: diphtheria and tetanus toxoids, acellular pertussis, Haemophilus influenza type b, and inactivated poliovirus (DTaP-Hib-IPV) vaccine (Pentacel™) has been added as a CHDP program benefit, effective August 15, 2008.

This Information Notice provides the new CHDP administration code 82 and billing and reimbursement information. An updated CHDP vaccine benefit and reimbursement table is enclosed that includes this new vaccine. A Vaccine for Children (VFC) Provider Letter that contains additional information on the vaccine, a document on Pentacel™ guidance, and a VFC order form are enclosed.

In June 2008, United States Food and Drug Administration (FDA) licensed a new combination vaccine, Pentacel™ (sanofi pasteur) for use in infants and young children. The Advisory Committee on Immunization Practices (ACIP) voted at their June 2008 meeting to recommend the inclusion of this new combination DTaP-Hib-IPV vaccine in the VFC program.

DTaP-Hib-IPV vaccine is a combination vaccine which includes diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV) component provided as a sterile liquid in a vial. This DTaP-IPV sterile liquid is used to reconstitute the lyophilized ActHIB vaccine (vial) component to form the DTaP-Hib-IPV vaccine.

DTaP-Hib-IPV vaccine is recommended for routine immunization to be given as a four-dose series administered intramuscularly at two months, four months, six months, and 15-18 months of age. DTaP-Hib-IPV vaccine may be given to children through four years, 11 months if catch-up is needed.

The minimal dosage intervals are four weeks between the first and second injections, four weeks between the second and third injections, and six months between the third and fourth injections. DTaP-Hib-IPV vaccine may be given at the same time as other recommended vaccines and should be given at a separate site with a different syringe.

ACIP recommends that whenever feasible, the same manufacturer's DTaP product should be used for the primary series. However, interchangeability of products is allowed and considered valid.

Until the Hib supply improves DTaP-Hib-IPV vaccine should be used only for the first three doses of the DTaP, IPV, and Hib vaccination series, except for children who are at increased risk of Hib disease. Children not receiving the 4<sup>th</sup> Hib dose will need to be recalled later for administration of the booster dose when supplies of Hib vaccine have improved.

#### **DTaP-Hib-IPV vaccine as a CHDP Program Benefit**

Effective August 15, 2008, CHDP will reimburse providers for the administration fee of DTaP-Hib-IPV vaccine to CHDP eligible infants and children; the vaccine will be provided at no charge by the VFC Program. The CHDP vaccine code is 82 and has the reimbursement rate of \$9.00 for the administration fee.

DTaP-Hib-IPV vaccine	82	VFC	2 months through 4 years, 11 months	\$9.00
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Code 82 is payable for four doses. DTaP-Hib-IPV vaccine has been added (mid October 2008) to the Vaccine Codes and Rates Table found in the rates max CHDP section of the CHDP Provider Manual.

#### **Reminder:**

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

#### **Billing Instructions for DTaP-Hib-IPV vaccine**

Please use the following instructions for billing for DTaP-Hib-IPV vaccine. Refer to the CHDP Provider Manual for additional information.

- Enter the CHDP Code number, 82, and DTaP-Hib-IPV vaccine on a blank line, under the immunization section of the PM 160 Confidential Screening/Billing Report.
- Enter a check mark in only one of the Immunization Outcome Columns (A or B) of the PM 160, as appropriate.
- Enter the administration fee in the Fees Column (Note: fees do not apply on the "Information Only" PM 160).
- If you have administered DTaP-Hib-IPV vaccine on or after August 15, 2008, and prior to this notice, you are entitled to reimbursement for the administration of this vaccine. Please submit a PM 160 for the \$9.00 administration fee if you have not been previously reimbursed for the vaccine by any source.

### **CHDP Vaccine Benefits and Reimbursement Table**

An updated CHDP Vaccine Benefit and Reimbursement Table are enclosed; it is dated September 15, 2008. The table includes the DTaP-Hib-IPV vaccine code and reimbursement rate.

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.

Marian Dalsey, M.D., M.P.H., Chief  
Children's Medical Services Branch

Enclosures

**CHDP Vaccine Codes and Rates  
September 15, 2008**

Vaccine	Code	Vaccine Source	Age	Rate <sup>1</sup>	Comment Required
DTaP	45	Vaccines For Children (VFC)	2 months thru 6 years, 11 months	\$9.00	
DTaP-Hib-IPV	82	Vaccines For Children (VFC)	2 months thru 4 years, 11 months	\$9.00	
DTaP-IPV	83	Vaccines For Children (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 (DECAVAC™)	58	VFC	7 years thru 18 years 11 months	\$9.00	
Td Adult	60	Purchased	7 years thru 20 years, 11 months	\$13.96	
Tdap	72	VFC	10 years thru 18 years 11 months	\$9.00	
	79	Purchased	19 years thru 20 years, 11 months	\$45.79	
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 <sup>2</sup>	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 (Ped./Adol.)	40	VFC	Birth thru 18 years, 11 months	\$9.00	
Hepatitis B Higher Dose (Adult)	42	VFC	11 years thru 15 years, 11 months <sup>3</sup>	\$9.00	(Use this code for two dose adolescent schedule)
Hepatitis B	51	Purchased	19 years thru 20 years, 11 months	\$67.98	
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 <sup>4</sup>	76	VFC	9 years thru 18 years, 11 months	\$9.00	
	77+ 78	Purchased	19 years thru 20 years 11 months	\$146.96	

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.
4. Only for females.

### CHDP Vaccine Codes and Rates

Vaccine	Code	Vaccine Source	Age	Rate <sup>1</sup>	Comment Required
Influenza <sup>5</sup>	53	VFC	6 months thru 18 years, 11 months	\$9.00	
	54	Purchased	36 months thru 20 years, 11 months	\$13.76	
Influenza Preservative Free <sup>5</sup>	80	Purchased	6 months thru 35 months	\$18.71	
FluMist <sup>5</sup>	71	VFC	2 years thru 18 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 <sup>6</sup>	34	Purchased	12 months thru 20 years, 11 months <sup>7</sup>	\$ 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 yrs
	70 + 73	Purchased	19 years thru 20 years 11 months	\$101.84	
Pediarix <sup>TM</sup>	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	
Pneumococcal Polysaccharide (23PS)	55	Purchased	2 years thru 20 years, 11 months	\$ 56.69	High risk factor
Pneumococcal, heptavalent (Prenar)	67	VFC	1 month thru 4 years, 11 months	\$ 9.00	
Rotavirus <sup>8</sup> (Rotateq <sup>TM</sup> )	75	VFC	6 weeks thru 32 weeks	\$9.00	
Rubella <sup>9</sup>	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.
5. For one dose annually, except for children less than 9 years who have never received an influenza immunization or only received one dose the first year of vaccination. These children should receive two doses, with a recommended interval of 28 days.
6. For individuals with a contraindication to rubella or mumps vaccine.
7. Measles vaccine (or, if not available, MMR) is recommended in children as young as 6 months, in outbreak situations or for international travel.
8. Oral vaccine, 3 doses (Rotateq<sup>TM</sup>).
9. For individuals with a contraindication to measles or mumps vaccine.



MARK B HORTON, MD, MSPH  
Director

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



ARNOLD SCHWARZENEGGER  
Governor

August 25, 2008

IZB-FY0809-03

TO: California Vaccines for Children (VFC) Program Providers

FROM: John Talarico, D.O., M.P.H., Interim Chief Immunization Branch *John Talarico, D.O., M.P.H.*

SUBJECT: PENTACEL® (DTaP-IPV/Hib COMBINATION VACCINE) IS NOW AVAILABLE FROM VFC

This memo is divided into sections to enable you to quickly access the information you need:

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## **SUMMARY**

In June 2008, United States Food and Drug Administration (FDA) licensed a new, combination vaccine, Pentacel™ (sanofi pasteur) for use in infants and young children. Pentacel™ is a diphtheria and tetanus toxoid and acellular pertussis adsorbed, inactivated poliovirus, and Haemophilus influenzae, type b conjugate (tetanus toxoid conjugate) vaccine. The Advisory Committee on Immunization Practices (ACIP) voted at their June 2008 meeting to recommend the inclusion of this new combination DTaP-IPV/Hib vaccine in the VFC program. Pentacel™ (DTaP-IPV/Hib vaccine) is now available from VFC in California. This document summarizes information about the use of Pentacel™ in the VFC program and updates on its use during the Hib-containing vaccine shortage in the United States.

## **BACKGROUND AND COMPOSITION**

Pentacel™ is a combination vaccine which includes diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus (DTaP-IPV) component provided as a sterile liquid in a vial. This DTaP-IPV sterile liquid is used to reconstitute the lyophilized ActHIB vaccine (vial) component to form the Pentacel™ vaccine (DTaP-IPV/ActHIB). Pentacel™ contains the same pertussis antigens as DAPTACEL™ but contains twice as much detoxified pertussis toxin (PT) and four times as much filamentous hemagglutinin (FHA) as DAPTACEL™.

It is important to carefully store the components together so that the DTaP-IPV vial (sanofi pasteur) provided in the Pentacel™ package is used to reconstitute the ActHIB™ component (vial). **Do not** use any other sterile liquid or DTaP-IPV vaccine to reconstitute the ActHIB™ component supplied in the Pentacel™ package.

## **RECOMMENDATIONS FOR VACCINE USE**

### **Eligible Groups for Receipt of VFC Supplies of Pentacel™**

VFC supplies of Pentacel™ may be given to VFC-eligible infants and young children aged 6 weeks through 4 years.

### **Licensed Dosing Schedule**

Pentacel™ is recommended for routine immunization to be given as a four-dose series administered intramuscularly at two months, four months, six months, and 15-18 months of age. The first dose may be given as early as six weeks of age.

### **Minimum ages and intervals:**

- Dose 1: minimum age of six weeks.
- Dose 2: minimum age of 10 weeks and four weeks minimum interval from first dose.
- Dose 3: minimum age of 14 weeks and four weeks minimum interval from second dose.
- Dose 4: minimum age of 12 months (determined by DTaP and Hib components) and a minimum interval of six months from third dose (determined by DTaP component). In contrast, the minimum interval for dose 3 to 4 is 8 weeks for Hib and 4 weeks for IPV).

**Valid Doses:** The schedule, minimum intervals, and minimum ages are determined by the individual components (DTaP, IPV, and Hib vaccines). If the minimum age and interval is met for some components, but not all, the components that have met both the minimum age and interval criteria may be counted and considered valid while components which have not met the minimum criteria will be considered invalid. ACIP recommends that whenever feasible, the same manufacturer's DTaP product should be used for the primary series. However, if the previous brand is unavailable or unknown, any brand may be used to complete the series. Do not defer a dose solely to wait for a specific DTaP vaccine brand to be available. Interchangeability of products is allowed and considered valid.

### **Recommended Schedule during Hib Shortage**

Due to the current Hib vaccine shortage, supplies of Hib-containing vaccines are still in very short supply despite the licensure of Pentacel™. At this time, it is not clear when the shortage of Hib-containing vaccines will resolve. Please do not use ActHIB™ or Pentacel™ for the fourth booster dose, except for children at high risk of Hib disease, because of the significant shortage of Hib-containing vaccines. Providers should continue to skip the booster dose of Hib vaccine for healthy children and recall them later for administration of the booster dose when supplies of Hib vaccine have improved. The Immunization Branch will update you when this Hib vaccine shortage situation changes.

The VFC Program still has some small supplies of PedvaxHIB™, prioritized for American Indian children, since they are at increased risk for Hib disease during the first six months of life. PedvaxHIB™ leads to a more rapid seroconversion in the first six months of life.

**Considerations when transitioning to Pentacel:** Many practices are currently using the combination DTaP-IPV-HBV vaccine (Pediarix™). We are requesting that each practice carefully consider the current choices of pentavalent vaccines (Pediarix™ and Pentacel™) and choose one formulation for administration in your practice to avoid confusion between the two pentavalent vaccines.

We are encouraging practices that are still not using a pentavalent vaccine during infancy to strongly consider using one of the available pentavalent vaccines to decrease the number of shots during infancy, which should benefit your families as well as your staff. We will work with you to transition your ordering to ensure that you have appropriate supplies of vaccine for your patients. If your practice is currently using single-antigen vaccines, you could begin using Pentacel™ as the first dose in the primary series for your two-month olds.

Infants already started on single-entity vaccines can finish the series with separately administered DTaP, IPV, and Hib vaccines. An alternative is to switch all infants to Pentacel™.

### **Administration**

Instructions for reconstitution and administration of Pentacel™ (see package insert for details):

- Thoroughly but gently shake the vial of DTaP-IPV component.  
Withdraw the entire liquid content into a syringe
- Insert the syringe needle through the stopper of the vial of lyophilized ActHIB™ vaccine component and inject the liquid into the vial.
- Shake vial thoroughly until a cloudy, uniform suspension results. Pentacel™ vaccine is uniform, cloudy, and white to off-white (yellow tinge) suspension. If extraneous

particulate matter or discoloration is seen, that dose of Pentacel should not be administered.

- After reconstitution, immediately withdraw all of the reconstituted Pentacel™ vaccine and administer intramuscularly.
- Pentacel™ should be used immediately after reconstitution.
- Store at 2 to 8 °C (35 to 46 °F). **Do not freeze.**

### **Administration with other vaccines**

Pentacel™ may be given at the same time as other recommended vaccines. Pentacel™ should be given at a separate site with a different syringe.

### **HOW SUPPLIED**

The vaccine is provided in a 5 dose package containing 5 vials of DTaP-IPV component to be used to reconstitute five single dose vials of lyophilized ActHIB™ vaccine component. The Product No. is 49281-510-05.

Neither the DTaP-IPV component nor the ActHIB™ vaccine component contains a preservative.

### **ORDERING AND BILLING**

#### **Order Calculations:**

If you will be planning to transition to use of Pentacel™ for your patients, we are requesting that you calculate your usage so that you do not order excess Hib-containing vaccine, Pediarix™, or other vaccines during your transition (see Appendix for more details). If you will be switching to Pentacel™, it may be easier to complete the primary series for patient who already started their vaccination series with your current vaccine regimen and begin starting new infants on Pentacel™ with the first 2 month visit. We are requesting those providers with large supplies of ActHIB™ who wish to switch to Pentacel™ to either begin using Pentacel™ when their supply is smaller so that ActHIB™ vaccine is not wasted or to contact the VFC program so that we may assist with this transition and prevent wasted vaccine.

If you are switching from Pediarix™ to Pentacel™, make sure to order appropriate quantities of single antigen hepatitis B vaccine for your inventory.

Please educate your entire office staff if you will be using Pentacel™, as it will affect your vaccine ordering, storage, administration and documentation. We have included a guidance document to assist you in administering the recommended immunizations for children using either Pentacel™ or Pediarix™.

#### **How to order**

VFC providers may order Pentacel™ using the attached VFC order form (DHS 8501, 9/08), which has been modified to include this new product. Remember to complete all sections of the VFC order form when submitting your vaccine request. Requests for this product should be included with your routine VFC vaccine request, as you will need to provide current vaccine

inventory on hand for all VFC vaccines and their corresponding usage in order for VFC to process your request. Please be aware that your request may be adjusted, especially during this introductory phase and while the Hib vaccine shortage lasts.

In order to prevent unnecessary vaccine wastage or overcrowding of vaccine storage units, providers who have decided to introduce Pentacel™ in their practice are encouraged to decrease on-hand supplies of other combination vaccines (or use up large inventories of single antigen DTaP and IPV) prior to placing an order. Additionally, once your practice has agreed to the introduction of this new product and determined the best immunization schedule, orders for a different combination vaccine in subsequent vaccine requests should not be considered.

Here are a few tips to follow when placing your Pentacel™ request:

- Verify that the incorporation of this new product has been approved by your practice.
- Due to limited supply during the vaccine's introductory phase, practices are encouraged to order a limited amount of this vaccine to vaccinate patients who will be starting their first immunization series (2-month series).
- Practices using single antigen vaccines (DTaP, IPV, Hib) should decrease orders for single antigen DTaP, IPV, and ActHIB™ by one dose for every dose of Pentacel™ requested.
- Practices currently using other combination vaccines must carefully check current inventory for combination vaccines, ActHIB™, DTaP, HepB, and IPV and develop a plan to deplete excess of inventory prior to placing a request for Pentacel™. It is the provider's responsibility to ensure all vaccines received from the VFC program are used prior to its expiration date or transferred to a VFC provider that may be able to use them.

Remember, managing on-hand inventory appropriately as this new vaccine is introduced in your practice will be key in preventing unnecessary vaccine wastage, and decrease the risk of improper vaccination.

### **Billing Information for VFC Vaccine**

CHDP: Claims may be submitted for doses of Pentacel™ administered on or after August 15, 2008. The CHDP administration fee is \$9.00 using CHDP code **82**.

However, providers should wait until notified by CHDP to submit claims. CHDP Provider Information Notices can be found at <http://www.dhcs.ca.gov/services/chdp/Pages/CHDPPLPIN.aspx>.

Medi-Cal Fee-For-Service (FFS): The CPT code for administration of Pentacel™ for Medi-Cal is **90698-SL**.

### Other codes for the use of Pentacel™ that is not supplied by VFC:

- The CPT code for Pentacel™ is **90698**.
- The CPT code for administration of Pentacel™ is **90465** if given alone, and **+90466** if given after (an) additional vaccine(s) at the same visit (e.g., if Pentacel™ and hepatitis

B vaccine are given at the same encounter then one of the vaccine administration codes will be 90465 and the other +90466).

- The ICD-9-CM code for Pentacel™ is **V06.8**.

## POTENTIAL VACCINE REACTIONS

Vaccine reactions were compared between Pentacel™ and DAPTACEL™+IPOL™+ActHIB™ for the first 3 doses and between Pentacel™ and DAPTACEL™ + ActHIB™ for dose four.

- Comparable solicited local and systemic adverse events
  - Tenderness, swelling, redness
  - Increased circumferential arm swelling
- Comparable overall rate of serious adverse events
- Comparable rates of fever > 38.5

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

## CONTRAINDICATIONS

Contraindications and Precautions are similar with the individual vaccines, DTaP, IPV and Hib:

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of Pentacel™ vaccine, any ingredient of Pentacel™ vaccine, or any other tetanus toxoid, diphtheria toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, or H. influenzae type b vaccine.
- As with other pertussis-containing vaccines:
  - Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause.
  - Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy. Pertussis-containing vaccines should not be administered to individuals with such conditions until the neurologic status is clarified and stabilized.

## PRECAUTIONS

- Moderate to severe illness.
- As with other DTaP-containing vaccines:
  - Temperature  $\geq 40.5^{\circ}\text{C}$  ( $\geq 105^{\circ}\text{F}$ ) within 48 hours of receipt of pertussi-containing vaccine, not attributable to another identifiable cause.
  - Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of receipt of pertussi-containing vaccine.
  - Persistent, inconsolable crying lasting  $\geq$  three hours within 48 hours of receipt of pertussi-containing vaccine.
  - Seizure with or without fever within three days of receipt of pertussi-containing vaccine.

- Guillain Barré syndrome within six weeks of receipt of a prior vaccine containing tetanus toxoid.

## **DOCUMENTATION**

Vaccine Information Statement (VIS) and fact sheet: A multiple vaccine VIS (1/30/08) is available for vaccines that are given between birth and the six months of age. This VIS or separate VIS for DTaP, IPV, and Hib can be used when administering Pentacel™. These VIS sheets can be found at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. Additional information on vaccines and vaccine preventable diseases can be found at: <http://www.cdc.gov/vaccines/>.

Product Insert: Refer to the product package insert for Pentacel™ for additional vaccine information. This may be found at <http://www.fda.gov/cber/products/pentacel.htm>.

VFC resolution No. 6/08-3 (Vaccines to Prevent Diphtheria, Tetanus and Pertussis):

VFC Resolution No. 6/08-4 (Vaccines to Prevent Poliomyelitis):

VFC Resolution No. 6/08-5 (Vaccines to Prevent *Haemophilus influenzae type b*):

The VFC resolutions for DTaP-, polio-, and Hib-containing vaccines have been updated and may be found at: <http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm>.

ACIP and AAP recommendations: ACIP recommendations for Pentacel™ will later be published at <http://www.cdc.gov/mmwr>. AAP vaccine recommendations and other information about vaccines are available to AAP members at <http://www.cispimmunize.org/>.

General Recommendations on Immunization (includes minimum ages and intervals):  
<http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf>

Vaccine Injury Compensation Program (VICP): Pentacel™ is covered by the federal VICP. Information on the federal VICP and DTaP-, polio-, and Hib-containing vaccines may be found at: <http://www.hrsa.gov/vaccinecompensation/>.

August 25, 2008

Enclosures: Order Form (9/08)

Guidance on the Use of Pentacel and Pediarix

cc: CDPH Immunization Branch Field Representatives  
Local Health Officers  
Local Health Department Immunization Coordinators  
Local Health Department CHDP Program Directors  
Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDHS  
Marian Dalsey, M.D., Acting Chief, Children Medical Services Branch, CDHS  
Michael Farber, M.D., Chief Medical Officer, Medi-Cal Managed Care,  
CDHS  
Shabbir Ahmad, D.V.M., M.S., Ph.D., Acting Chief, Maternal, Child and Adolescent Health  
Program, CDPH  
Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB  
Robert Heiligman, M.D., Medical Policy Section, Medi-Cal Benefits, Waiver  
Analysis and Rates Division, CDHS  
Narinder Dhaliwal, M.D. Medical Policy Section, Medi-Cal Benefits,  
Waiver Analysis and Rates Division, CDHS  
Alan Morita, Pharm.D., Medi-Cal Pharmacy Policy Branch, CDHS  
Kathy Chance, M.D., Children Medical Services Branch, CDHS

# VACCINES FOR CHILDREN (VFC) PROGRAM VACCINE ORDER FORM FAX TO:(877) 329-9832

NAME OF PHYSICIAN'S OFFICE, PRACTICE, CLINIC, ETC.		DATE	VFC PIN NUMBER (6 digit)
DELIVERY ADDRESS (Number and Street—No P.O. Boxes)		CONTACT PERSON	
<input type="checkbox"/> CHECK HERE IF THIS IS A NEW ADDRESS.		CITY	ZIP CODE
		TELEPHONE:	COUNTY:
FAX:	EMAIL:	STORAGE CAPACITY (Check All That Apply)	
DELIVERY: Check all days and times you may receive vaccine. If closed during lunch hour, please specify.	Tue From: to: (Closed for lunch from: to: ) Wed From: to: (Closed for lunch from: to: ) Thur From: to: (Closed for lunch from: to: ) Fri From: to: (Closed for lunch from: to: )	<input type="checkbox"/> Small Unit/Under the Counter Refrigerator <input type="checkbox"/> Refrigerator/Freezer Combination <input type="checkbox"/> Stand alone freezer <input type="checkbox"/> Commercial/Laboratory Grade Unit # of units _____ # of units _____ # of units _____ # of units _____	

**Please complete all sections on this order form in order for VFC to process your vaccine order.**

Vaccines	DOSES USED	VACCINE INVENTORY (DOSES ON HAND)			NEW VACCINE ORDER		
	Number of doses used since last order. Enter "0" if none	Number of doses on hand (Current Inventory)	Lot Number	Expiration Date	Vaccine (Circle Choice)	Doses Requested (Multiples of 10)	Packaging (Check preferred presentation)

**REGULAR ORDER VFC VACCINES**

DTaP					DAPTACEL®		Single dose vials – 10 per box
					Tripedia®		Single dose vials – 10 per box
					Infanrix®		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 5 per box
DTaP/Hepatitis B/IPV					Pediarix®		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 5 per box
DTaP/IPV/Hib					Pentacel®		Single dose vials – 5 per box
Hepatitis A					VAQTA®		Currently not available.
					Havrix®		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 5 per box
Hepatitis B					ENGERIX B®		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 5 per box
					RECOMBIVAX®		Single dose vials – 10 per box
Hepatitis B/Hib					COMVAX®		Currently not available.
Hib					PedvaxHIB®		Currently not available.
					ActHIB®		Single dose vials – 5 per box
HPV					Gardasil®		Single dose vials – 10 per box
IPV					IPOL®		10 dose vial
Meningococcal Conjugate					Menactra™		Single dose vials – 5 per box
Pneumococcal Conjugate					Prevnar®		Single dose syringes – 10 per box
Rotavirus					RotaTeq®		Single dose tubes – 10 per box
Td					DECAVAC™		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 10 per box
Tdap					ADACEL		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 5 per box
					BOOSTRIX		<input type="checkbox"/> Single dose vials – 10 per box <input type="checkbox"/> Single dose syringes – 5 per box

**VFC VACCINES STORED IN THE FREEZER**

Varicella					VARIVAX®		Single dose vials – 10 per box
MMR/Varicella					ProQuad®		Currently not available. Please order single antigen varicella and MMR vaccines instead.
MMR					MMR-II®		Single dose vials – 10 per box

**IMPORTANT: IF MY VACCINE BRAND CHOICE AND PACKAGING IS NOT AVAILABLE:**  
 Send another vaccine brand/packaging     Send the vaccine brand/packaging I circled above when it is available  
**Place your order with sufficient stock on hand to allow 3-4 weeks for the processing and delivery of your vaccine order.**





# Instructions for Completing the VFC Vaccine Order Form

In order to ensure that your vaccine order is processed as quickly as possible, the VFC Vaccine Order form **must** be completely filled out. Fill in all blank sections of the form. Orders submitted in outdated forms may delay the processing of your vaccine order.

## Instructions:

**1. Enter your clinic's PIN number.**

The PIN number is the six-digit Provider Identification Number assigned to your clinic upon enrolling in the VFC Program. (This is not your medical license or CHDP/Medi-Cal provider numbers). Your PIN can be found in the upper, left portion of one of your VFC shipping packing slips invoices. You may contact the VFC Office to obtain your PIN #.

**2. Use the same facility name that you used when enrolling in the VFC Program.**

The facility name can be found on the packing slips that accompany the vaccine shipments. Do not change this VFC facility name without first notifying the VFC Program in writing, even if the clinic name has changed or is incorrect.

**3. Specify the address where the VFC Program should deliver vaccines.**

Check the appropriate box on the order form if this is a new address. (Remember to include a letter regarding the change of address with your vaccine order.)

**4. Specify all days and times during which you can receive delivery of VFC vaccine.**

The VFC Program's wholesale distributor delivers vaccine Tuesday through Friday only. When specifying delivery times, take into account times of the day during which you cannot receive deliveries of VFC vaccine (e.g., lunch).

**5. Record usage of all VFC vaccine you have administered since your last order.**

This Information is easily obtained from a usage log or any other usage reports (e.g., Registry-generated usage reports).

**6. List current inventory of all VFC vaccines when completing the order form.**

**(Do not report inventories of privately purchased vaccines)**

List the amount of VFC vaccine on-hand in your refrigerator and freezer, along with their corresponding lot numbers and expiration dates. You may use a separate sheet of paper to record additional lot numbers if needed. You may also attach a registry-generated inventory report outlining detailed information on lot numbers and expiration dates. However, you must still record the total number of doses on-hand in the order form. This will assist the Customer Service Representatives in approving your vaccine order in a timely manner.

**7. Select product choice and indicate the number of vaccine doses requested.**

The number of doses requested must be in multiples of 10, since most products are shipped in packages of 10 single dose vials/syringes or 10-dose multi-dose vials.

**8. Indicate packaging preference for requested product.**

When indicated, check your choice of product presentation or packaging. If you do not specify a vaccine preference or packaging, the VFC Program will send vaccine that is currently on stock.

**When Completed:**

**Fax to:** (877) 329-9832 (toll-free)

**OR**

**Mail to:** Vaccines for Children Program  
California Department of Public Health,  
Immunization Branch  
850 Marina Bay Parkway Building P, 2nd Floor  
Richmond, CA 94804

**Always keep a copy for your records!**

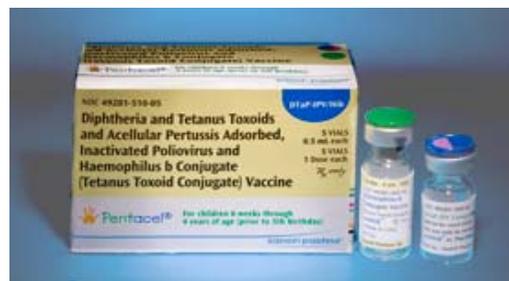
**For Questions Call:** (877) 243-8832

**OR**

**Contact your local VFC Representative**

## Guidance on the use of Pentacel and Pediarix August 2008

Pentacel is a combination vaccine that contains DTaP, IPV and Hib vaccines. Pentacel is supplied as single-dose vials, 5 doses to a package. A single-dose vial of liquid DTaP-IPV vaccine is used to reconstitute a single-dose vial of lyophilized ActHIB vaccine. The vaccine must be kept at refrigerator temperature (35°-46° F) at all times. Pentacel must never be frozen. Vaccine exposed to freezing temperature must not be used.



### IMPORTANT NOTE:

The availability of Pentacel will improve the Hib vaccine supply situation in the United States. However, the availability of Pentacel is not sufficient to reinstate the last (booster) dose of the Hib vaccine series (i.e., the dose administered after the first birthday). Although Pentacel is licensed by FDA for the fourth dose in the DTaP, IPV and Hib series, providers should NOT use it for the fourth dose until there is further improvement in the Hib vaccine supply (anticipated for the last quarter of 2008). **Until the Hib supply improves Pentacel should be used ONLY for the first three doses of the DTaP, IPV, and Hib vaccination series, except as noted below.**

As with all combination vaccines, there are no special rules for Pentacel, except as determined by FDA licensure of the product (i.e., the maximum age for any dose-see below). The schedule, minimum intervals, and minimum ages are determined by the individual components. The recommended schedule for Pentacel is similar to those for DTaP and ActHib with doses at 2, 4, 6, and 15 through 18 months of age.

Pentacel can be administered to any child 6 weeks through 4 years of age, without a contraindication to any component, for whom DTaP, IPV, and Hib vaccines are indicated. As stated on the childhood immunization schedule, **a combination vaccine, including Pentacel, may be used whenever any component(s) of the combination is indicated and no other component of the vaccine is contraindicated.** This means that Pentacel can be used when a child needs one or two components, but does not need the others.

Contraindications and precautions for Pentacel are the same as those for DTaP, IPV, and Hib vaccines.

The following minimum ages and intervals are defined for the component vaccines in various ACIP statements, and in particular in Table 1 of the 2006 version of the *General Recommendations on Immunization* (<http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf>, page 3) and on page 31-32 of the 2006 AAP *Red Book*.

Parameter	Age/interval
Minimum age for any dose	6 weeks
Minimum interval for doses 1 and 2	4 weeks
Minimum age for dose 2	10 weeks
Minimum interval for doses 2 and 3	4 weeks
Minimum age for dose 3	14 weeks
Minimum interval for dose 3 and 4	<b>6 months</b> (determined by DTaP component; minimum interval for dose 3-4 is two months for Hib and four weeks for IPV)
Minimum age for dose 4	<b>12 months</b> (determined by DTaP and Hib components). Note that both the minimum interval AND age must be met for the fourth dose of DTaP or Hib (as Pentacel or any other formulation) to be counted as valid
Maximum age for <b>any</b> dose	4 years, 364 days (i.e., do not administer at age 5 years or older)

Please refer to the tables below for guidance on schedules for Pentacel, Pediarix and the single antigen series for Hep B, Hib, IPV DTaP for healthy children\* during the Hib vaccine shortage.

## Examples of Schedules Using Pentacel and/or Pediarix for Healthy Children\* During the Hib Shortage

The first two tables below provide examples of how to introduce Pentacel in your practice using two different schedules. The second two tables review the schedules for the single antigen and Pediarix series for Hep B, IPV, Hib and DTaP.

### Schedule for Hep B, Hib\*, IPV, and DTaP Using Pentacel for All Doses

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B		Hep B		
				DTaP	DTaP
					IPV
	Pentacel	Pentacel	Pentacel		

### Schedule for Hep B, Hib\*, IPV, and DTaP Using Pentacel For First Dose Only and Pediarix for Remainder of Doses

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B				
		Hib	Hib		
				DTaP	DTaP
					IPV
	Pentacel				
		Pediarix	Pediarix		

### Schedule for Hep B, Hib\*, DTaP and IPV Without Pentacel or Pediarix

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B		Hep B		
	Hib	Hib	Hib		
	DTaP	DTaP	DTaP	DTaP	DTaP
	IPV	IPV	IPV		IPV

### Schedule for Hep B, Hib\*, IPV, and DTaP Using Pediarix Only (No Pentacel)

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B					
	Hib	Hib	Hib		
				DTaP	DTaP
					IPV
	Pediarix	Pediarix	Pediarix		

Pentacel contains DTaP, IPV and Hib. Pediarix contains DTaP, IPV, and Hep B

Neither Pentacel nor Pediarix should be used prior to 6 weeks of age. In general ACIP recommends the same brand of DTaP be used for all doses of the series. However, different brands can be used if the providers does not know or have available the brand of DTaP used for prior doses.

\*When supplies are sufficient an additional dose of Hib vaccine (single antigen or as part of a combination vaccine) is recommended for healthy children at 12 through 15 months of age (at least 2 months after the prior dose). Either Pentacel or single antigen Hib vaccine may be used at 12 through 15 months of age for children who are at increased risk of Hib disease or who have not completed a complete primary Hib schedule. If Pentacel is administered at 12 through 15 months of age a dose of DTaP at 15 through 18 months of age is not needed. See *MMWR* 2007;56(No.50):1318-1320 for additional details.

Questions or comments on this document should be directed your state or local immunization program, or to CDC by e-mail at [nipinfo@cdc.gov](mailto:nipinfo@cdc.gov).