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

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TO: California Vaccines for Children (VFC) Program Providers

FROM: John Talarico, D.O., M.P.H., Interim Chief
Immunization Branch, Division of Communicable Disease Control, Center for Infectious Diseases

SUBJECT: KINRIX® (DTaP-IPV COMBINATION VACCINE) IS NOW AVAILABLE FROM VFC

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

SUMMARY

In June 2008, United States Food and Drug Administration (FDA) licensed a new, combination vaccine, Kinrix™ (GlaxoSmithKline), for use in children ages 4 through 6 years. Kinrix™ is designed specifically for use as the fifth DTaP dose and fourth IPV dose prior to Kindergarten. The Advisory Committee on Immunization Practices (ACIP) voted at their June 2008 meeting to recommend the inclusion of this new combination DTaP-IPV vaccine in the Vaccines for Children (VFC) program. Kinrix™ (DTaP-IPV vaccine) is now available from VFC in California. This document summarizes information about the use of Kinrix™ in the VFC program. Each office should ensure that staff involved in administering Kinrix™ are appropriately trained and competent in the relevant details of this letter.

BACKGROUND AND COMPOSITION

Kinrix™ includes diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP) and inactivated poliovirus (IPV). It is a noninfectious, sterile vaccine for intramuscular administration. The diphtheria, tetanus, and pertussis components of Kinrix™ are the same as those in Infanrix™ (DTaP) and Pediarix™ (DTaP-hepatitis B-IPV) and the poliovirus component is the same as that in Pediarix™. The acellular pertussis antigens included in the vaccine are inactivated PT, FHA, and pertactin. Neomycin sulfate and polymyxin B are used in the poliovirus vaccine manufacturing process and may be present in the final vaccine in small quantities.

Immunologic response to Kinrix™ was compared to Infanrix™ (DTaP) and IPV (sanofi pasteur) administered concomitantly at separate sites. Kinrix™ was shown to be non-inferior to Infanrix™ and IPV administered separately, assessing the booster responses to DTaP antigens and post-vaccination GMTs for anti-poliovirus antibodies.

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of Kinrix™

VFC supplies of Kinrix™ may be given to VFC-eligible children aged 4 years through 6 years.

Licensed Dosing Schedule

Kinrix™ is indicated for use as the fifth dose of DTaP and fourth dose of IPV in children aged 4 through 6 years who received DTaP (Infanrix) ™and/or DTaP-Hepatitis B-IPV (Pediarix™) as the first 3 doses and DTaP (Infanrix™) as the fourth dose. **Please note that this vaccine is not licensed for use in the primary series and should not be given to children younger than 4 years of age.**

Minimum ages and intervals:

The schedule, minimum intervals, and minimum ages are determined by the individual components (DTaP and IPV vaccines). If the minimum age and interval is met for one component, but not both, the component that has met both the interval criteria should be considered valid while the component which has not met the minimum age or interval criterion should be considered invalid. See ACIP's General Recommendations on Immunization for specific minimum intervals and ages at http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf.

ACIP recommends that whenever feasible, the same manufacturer's DTaP brand should be used to complete the series. However, if the previous brand is unavailable or unknown, any brand may be used to complete the series. Do not defer immunization solely to wait for a specific DTaP vaccine brand to be available. Interchangeability of products is allowed and considered valid.

Vaccine Storage

Kinrix™ should be stored at 2 º to 8 ºC (35 º to 46ºF). Vaccine must not be frozen.

Administration:

Shake vigorously to obtain a homogeneous suspension. Do not use if resuspension does not

occur with vigorous shaking. Vaccine should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Completely withdraw suspension from the vial. Kinrix™ is to be administered by an intramuscular injection (0.5 mL dose). The preferred site of administration is the deltoid muscle of the upper arm.

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

POTENTIAL VACCINE REACTIONS

Vaccine reactions within 4 days of administration were compared between Kinrix™ and Infanrix™+IPV (sanofi pasteur) when c administered with MMR vaccine (Merck).

	KINRIX	**INFANRIX + IPV**
Local Reaction	**N=3,121-3,128**	**N=1,039-1,043**
Pain, any	57.0%*	53.3%
Pain, grade 3	1.6%*	0.6%
Redness	36.6%	36.6%
Arm circumference increase, any	36.0%	37.8%
Swelling, any	26.0%	27.0%
General	**N=3,037-3,120**	**N=993-1,036**
Drowsiness	19.1%	17.5%
Fever >100.4	6.5%*	4.4%
Fever > 102.2	1.1%	1.1%
Loss of appetite	15.5%	16.0%

*Statistically higher than comparison group ($p<0.05$)

There was no increase in reported serious adverse events in the 31 day period following study vaccination with Kinrix™ compared with Infanrix™+IPV

Report suspected reactions to Kinrix™ 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 and IPV:

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of Kinrix™ vaccine, any ingredient of Kinrix™ vaccine, including neomycin and polymyxin, or any other tetanus toxoid, diphtheria toxoid, pertussis-containing vaccine, or inactivated poliovirus vaccine. Persons with history of anaphylaxis to latex should not receive Kinrix™ in the prefilled syringe formulation; however, they may receive Kinrix™ from the vial formulation.
- 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 ≥40.5ºC (≥105ºF) within 48 hours of prior pertussis vaccination, not attributable to another identifiable cause.
  - Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of pertussis vaccination.
  - Persistent, inconsolable crying lasting ≥ three hours within 48 hours of prior pertussis vaccination.
  - Seizure with or without fever within three days of prior pertussis vaccination.
  - Guillain Barré syndrome within six weeks of receipt of a prior vaccine containing tetanus toxoid.

HOW SUPPLIED

Kinrix™ is provided in two formats:

1) Single dose 0.5 mL vials in a package of 10 (NDC 58160-812-11)
2) Single-dose 0.5 mL prefilled disposable TIP-LOK syringes (packaged without needles) in a package of 5 (NDC 58160-812-46)

Kinrix™ does not contain a preservative. The tip cap and the rubber plunger of the needleless prefilled syringes contain dry natural latex rubber. The vial stopper is latex-free.

ORDERING AND BILLING

How to order
VFC Providers may order Kinrix™ using the attached revised order form (DHS 8501 (11/08). Remember to complete all the boxes in the four columns of the order form. Maintain a copy of your order forms for your office files. Please be aware that your orders of Kinrix™ may be adjusted, especially during this introductory phase.

We suggest you include your initial vaccine request along with your routine vaccine order and according to the assigned order frequency for your practice.

Billing Information for VFC Vaccine
CHDP: Claims may be submitted for doses of Kinrix™ administered on or after September 15, 2008. The CHDP administration fee is $9.00 using CHDP code **83**. 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 Kinrix™ for Medi-Cal is **90696-SL.**

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

- The CPT code for Kinrix™ is **90696**.
- The ICD-9-CM code for Kinrix™ is **V06.3**.

DOCUMENTATION

Vaccine Information Statement (VIS) and fact sheet: VISs for DTaP and IPV can be used when administering Kinrix™. 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 Kinrix™ for additional vaccine information. This may be found at http://www.fda.gov/cber/products/kinrix.htm.

VFC resolution No. 6/08-3 (Vaccines to Prevent Diphtheria, Tetanus and Pertussis):
VFC Resolution No. 6/08-4 (Vaccines to Prevent Poliomyelitis):
The VFC resolutions for DTaP- and polio-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 Kinrix™ can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a4.htm. 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): Kinrix™ is covered by the federal VICP. Information on the federal VICP and DTaP- and polio-containing vaccines may be found at: http://www.hrsa.gov/vaccinecompensation/.

Enclosures: Order Form (11/08)

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