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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: QUADRACEL (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:

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SUMMARY

In 2015, the Food and Drug Administration licensed an additional combined diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP) and inactivated poliovirus (IPV) vaccine (DTaP-IPV) (Quadracel, Sanofi Pasteur Inc.). Quadracel is the second DTaP-IPV vaccine to be licensed for use for children aged 4 through 6 years in the United States. Quadracel is approved for administration as a fifth dose in the DTaP series and as a fourth or fifth dose in the IPV series in children aged 4 through 6 years who have received 4 doses of DTaP-IPV-Hib (Pentacel, Sanofi Pasteur) and/or DTaP (DAPTACEL, Sanofi Pasteur) vaccine (2,3).



In 2017, Quadracel (DTaP-IPV vaccine) has become available for order. This document summarizes information about the use of Quadracel in the California VFC program.

BACKGROUND AND COMPOSITION

Quadracel is a sterile suspension for intramuscular injection. The diphtheria, tetanus, and pertussis components of Quadracel are the same as those in Pentacel or DAPTACEL, and the poliovirus component is the same as that in Pentacel or IPOL. The acellular pertussis antigens included in the vaccine are inactivated PT, FHA, pertactin, and fimbriae types 2 and 3. Neomycin sulfate and polymyxin B may be present in the final vaccine in small quantities. Quadracel does not contain a preservative.

In a clinical trial, the immunologic response to Quadracel was comparable to DAPTACEL + IPOL (sanofi pasteur) administered concomitantly at separate sites.

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of Quadracel

VFC supplies of Quadracel may be given to VFC-eligible children aged 4 years through 6 years. It is approved for use as the fifth dose in the DTaP immunization series and the fourth or fifth dose in the polio immunization series.

Licensed Dosing Schedule

Quadracel is recommended for routine immunization to be given as a booster administered intramuscularly at ages 4 through 6 years. Please note that this vaccine is not licensed for use in the primary series, for children younger than 4 years of age or older than 6 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.

DTaP, Dose 5

- Minimum age of 4 years.
- Minimum interval of 6 months after dose 4

IPV, Dose 4

- Minimum age of 4 years.
- Minimum interval of 6 months after dose 3

The 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

Quadracel should be stored at 2° to 8°C (36° to 46°F). Do not freeze. Product which has been exposed to freezing should not be used. Do not use after expiration date shown on the label.

Administration

Just before use, shake the vial well, until a uniform, white, cloudy suspension results. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the product should not be administered. Quadracel should not be combined through reconstitution or mixed with any other vaccine.

Using a sterile needle and syringe and aseptic technique, withdraw and administer a 0.5 mL dose of Quadracel vaccine intramuscularly into the deltoid muscle of the upper arm. Quadracel is for intramuscular use only.

Administration with other vaccines

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

HOW SUPPLIED

Quadracel is supplied in a single-dose vial (NDC No. 49281-562-58) in packages of 10 vials (NDC No. 49281-562-10).

Quadracel does not contain a preservative. The vial stopper for this product is not made with natural latex rubber.

ORDERING AND BILLING

VFC Ordering

Quadracel is now available for VFC Providers to order through MyVFCvaccines.org. Providers wishing to transition to Quadracel should submit requests for this product during their routine ordering cycle, according to the clinic's assigned order frequency.

In order to prevent vaccine wastage, new orders must be placed taking into consideration current vaccine supply.

Please review VFC's standard guidelines for the introduction of a new vaccine product or brand in your practice:

- Verify that the introduction of this product has been approved by your practice's medical director or Physician-in-Chief.
- Please educate your entire office staff if you will be switching to Quadracel as it will affect your vaccine ordering, storage, administration, and documentation.
 - Ensure healthcare providers in your practice review information in this letter, immunization schedules, minimum intervals and licensed age ranges to avoid errors in administration. Information for these two products can be found at: <http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.
 - Complete staff education, update clinic protocols and forms, as needed, and identify and label space in your refrigerator prior to ordering a new product.
- Practices currently using either single vaccine components (DTaP and IPV) or another combination vaccine in children 4 through 6 years of age must carefully check current inventory and develop a plan to use up inventory prior to placing a request for Quadracel.
- Offices must choose only one combination DTaP-IPV vaccine formulation for use (either Kinrix or Quadracel) to avoid confusion.
- To prevent delays in the processing of your order, make sure to add a note in the comment field on the order form indicating that your clinic is ready to order a new product. If switching combination brands, then note that your clinic provider of record has approved a switch in vaccine combination brands.

Remember, managing on-hand inventory appropriately as this vaccine is introduced in your practice will be key in preventing unnecessary vaccine wastage and decreasing the risk of improper vaccination. It is the provider's responsibility to ensure all vaccines received from the VFC program are used prior to their expiration date or transferred to a VFC provider that may be able to use them. Viable unused vaccine doses CANNOT be returned to the VFC Program.

If vaccine administration errors do occur, please report details of the error to <http://verp.ismp.org/>.

CHDP

Claims may be submitted for VFC-supplied doses of Quadracel administered to CHDP-eligible patients through age 18 years. Please refer to the [CHDP Provider manual](#) and relevant [CHDP Provider Information Notice](#). Further updates about Quadracel vaccine from the CHDP program will follow. CHDP providers with additional questions are advised to contact their County CHDP Program at <http://www.dhcs.ca.gov/services/chdp/Pages/CountyOffices.aspx>.

Medi-Cal Fee-For-Service (FFS)

To bill Medi-Cal FFS for administration of VFC-supplied doses of Quadracel, use the CPT code and modifier **90696-SL**. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS eligible patients.

For specific information and details on Medi-Cal billing, please refer to the Medi-Cal Provider Manual section on the VFC Program. Providers with questions on Medi-Cal billing policies and procedures and Provider Manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

Medi-Cal Managed Care

Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

Other codes for the use of Quadracel that is not supplied by VFC

- The CPT code for Quadracel is **90696**
- The ICD-10 diagnosis code for Quadracel is **Z23**
- Administration WITH qualified counseling CPT Code is **90460** (1 unit) or **90461** (3 units)
- Administration without qualified counseling CPT Code is **90471** (1 unit) or **90472** (1 unit)

POTENTIAL VACCINE REACTIONS

In a clinical study, the most common solicited injection site reactions to Quadracel were pain (>75%), increase in arm circumference (>65%), erythema (>55%), and swelling (>40%). Common solicited systemic reactions were myalgia (>50%), malaise (>35%), and headache (>15%).

During the clinical study, within 28 days 0.1% of subjects (3/2733) receiving Quadracel experienced a serious adverse event (SAE). During the same time period, 0.2% of subjects (1/621) receiving DAPTACEL + IPOL group experienced a SAE. Within the 6-month follow-up period after vaccination, SAEs were reported in 0.8% of subjects (21/2733) who received Quadracel and 0.5% of subjects (3/621) who received DAPTACEL + IPOL vaccines, none of which were assessed as related to vaccination.

Report suspected reactions to Quadracel 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 Quadracel vaccine, any ingredient of Quadracel vaccine, including neomycin and polymyxin, or any other tetanus toxoid, diphtheria toxoid, pertussis-containing vaccine, or inactivated poliovirus 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 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 \geq 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.

DOCUMENTATION

Vaccine Information Statement (VIS) and fact sheet: VISs for DTaP and IPV can be used when administering Quadracel. These VIS sheets can be found at <http://www.cdc.gov/vaccines/pubs/vis/default.h>. Additional information on vaccines and vaccine preventable diseases can be found at: <http://www.cdc.gov/vaccines/>.

Product Insert: Please refer to the product package insert for Quadracel for additional vaccine information. This may be found at <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm439856.htm>

VFC resolution No. 10/12-1 (Vaccines to Prevent Diphtheria, Tetanus and Pertussis):
VFC Resolution No. 6/09-1 (Vaccines to Prevent Poliomyelitis):

The VFC resolutions for DTaP- and polio-containing vaccines have been updated and may be found at: <https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>.

Guidance and recommendations: CDC guidance for Quadracel is published at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a5.htm>. The AAP vaccine recommendations and other information about vaccines are available to AAP members at <http://www.cispimmunize.org/>.

General Best Practice Guidelines for Immunization (includes minimum ages and intervals): <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>.

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

Enclosures: Immunization Schedule with Combination Vaccines, IMM-922 (4/17)
Vaccine Fact Sheet DTaP-IPV Combination Vaccine, IMM-106 (3/17)

cc: CDPH Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Local Health Department CHDP Program Directors