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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: Vaxelis™ (DTaP-IPV-Hib-HepB Vaccine) Available Through the VFC Program

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SUMMARY

This document summarizes the availability and use of Vaxelis™ in the California VFC program and immunization recommendations. On December 21, 2018, the United States (U.S.) Food and Drug Administration (FDA) approved the licensure of Vaxelis™, for the prevention of:

- Diphtheria, tetanus, pertussis, and poliomyelitis
 - Via components from Sanofi Pasteur
- *Haemophilus influenzae* type b invasive disease and hepatitis B
 - Via components from Merck

Vaxelis™ is approved by FDA for use as a 3-dose series in children 6 weeks through 4 years of age (prior to the 5th birthday).

BACKGROUND AND COMPOSITION

Each 0.5mL dose of Vaxelis™ contains 15 Lf diphtheria toxoid, 5 Lf tetanus toxoid, acellular pertussis antigens [20 mcg detoxified pertussis toxin (PT), 20 mcg filamentous hemagglutinin (FHA), 3 mcg pertactin (PRN), 5 mcg fimbriae types 2 and 3 (FIM)], inactivated polioviruses [29 D-antigen units (DU) Type 1 (Mahoney), 7 DU Type 2 (MEF-1), 26 DU Type 3 (Saukett)], 3 mcg polyribosylribitol phosphate (PRP) of *H. influenzae* type b covalently bound to 50 mcg of the outer membrane protein complex (OMPC) of *Neisseria meningitidis* serogroup B, and 10 mcg hepatitis B surface antigen (HBsAg). Each 0.5 mL dose contains 319 mcg aluminum from aluminum salts used as adjuvants.

Vaxelis™ does not contain a preservative. The vial stopper, syringe plunger stopper, and syringe tip cap are not made with natural rubber latex.

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of Vaxelis™

VFC supplies of Vaxelis™ may be given to any VFC-eligible child ages 6 weeks through 4 years for the three-dose series against diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and *H. influenzae* type b invasive disease. Per [VFC resolution](#), the combined DTaP-IPV-Hib-HepB vaccine may be used when any component of the combination is indicated, and if other components are not contraindicated.

Licensed Dosing Schedule

Vaxelis™ is to be administered as a three-dose series at 2, 4, and 6 months of age. The first dose may be given as early as 6 weeks of age. Three doses of Vaxelis™ constitute a primary immunization course against diphtheria, tetanus, *H. influenzae* type b invasive disease and poliomyelitis. Vaxelis™ may be used to complete the hepatitis B immunization series. A three-dose series of Vaxelis™ does **not** constitute a primary immunization series against pertussis; an additional dose of pertussis-containing vaccine is needed to complete the primary series.

Current ACIP Recommendations

Per [ACIP recommendations](#), hexavalent Vaxelis™ (DTaP-IPV-Hib-HepB) is indicated for use in infants at ages 2, 4, and 6 months.

For the prevention of diphtheria, tetanus and pertussis, children are recommended to receive a three-dose primary series of DTaP, at ages 2, 4, and 6 months, and booster doses at ages 15-18 months and 4-6 years. Vaxelis™ can be used for the first three doses of the recommended DTaP series but should not be used for the fourth or fifth dose. Vaxelis™ is not recommended for use for the third dose of the primary series on an accelerated schedule at 4-week intervals for the prevention of pertussis.

For prevention of poliomyelitis, children are recommended to receive four doses of IPV, at ages 2, 4, 6-18 months, and 4-6 years. Vaxelis™ may be used for the first three doses of the IPV series but is not indicated for the fourth dose.

For prevention of invasive *H. influenzae* type b disease, children are recommended to receive a primary series (two or three doses, depending on the vaccine used) of a Hib conjugate vaccine and a booster dose of vaccine at age 12-15 months. Vaxelis™ is licensed as a three-dose primary series. Therefore, three doses of a Hib conjugate-containing vaccine are needed to complete the primary series if Vaxelis™ is used for any doses. Vaxelis™ should not be used for the booster dose (after completion of the three-dose primary series).

For prevention of hepatitis B, children are recommended to receive three doses of a hepatitis B vaccine at ages 0, 1-2, and 6-18 months, with variations depending on the maternal hepatitis B infection status, infant birthweight, and vaccine manufacturer. Vaxelis™ is not licensed for the birth dose but can be used for doses given at ages of at least 6 weeks to infants of HBsAg-negative mothers. In addition to this FDA-approved use, three doses of Vaxelis™ can be administered to an infant aged at least 6 weeks born to a woman who is HBsAg-positive or whose HBsAg status is unknown. For adequate immune response, the last dose of HepB vaccine should be given at age ≥ 24 weeks; therefore, the third dose of Vaxelis™ is not recommended to be given before age 24 weeks. If it is given earlier, an additional dose of HepB vaccine should be given at age of at least 24 weeks, maintaining proper spacing with previous doses.

Vaxelis™ can be used for children aged younger than 5 years requiring a catch-up schedule. However, vaccine doses should not be administered at intervals less than the minimum intervals provided in Table 3–1 of the [General Best Practices Guidelines](#).

Minimum Ages and Intervals

- Minimum age for any dose: 6 weeks
- Minimum interval between dose 1 and 2: 4 weeks
- Minimum age for dose 2: 10 weeks
- Minimum interval between dose 2 and 3: 4 weeks
- Minimum age for dose 3: 24 weeks
- Maximum age for any dose: 4 years, 364 days

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) to a previous dose of Vaxelis™, any ingredient of Vaxelis™, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or Haemophilus influenzae type b vaccine.
- Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause.
- Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.

Precautions

- Carefully consider benefits and risks before administering Vaxelis™ to persons with a history of:
 - fever $\geq 40.5^{\circ}\text{C}$ ($\geq 105^{\circ}\text{F}$), hypotonic-hyporesponsive episode (HHE), or persistent, inconsolable crying lasting ≥ 3 hours within 48 hours after a previous pertussis-containing vaccine.
 - seizures within 3 days after a previous pertussis-containing vaccine.
- If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Vaxelis™.
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including Vaxelis™, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.
- Urine antigen detection may not have definitive diagnostic value in suspected *H. influenzae* type b disease temporarily following vaccination with Vaxelis™.

Vaccine Information Statement (VIS)

The most current version of the [VIS for Multiple Vaccines](#) must be provided to a parent or guardian before the child receives each dose of the vaccine. The VIS for multiple vaccines can be used in place of individual VISs for DTaP, Hib, Hepatitis B, and Polio

vaccines. Each time a VIS is provided, the following information must be included in each patient's permanent medical record:

- Edition date of the current Vaccine Information Statement that was provided.
- Date that the VIS was provided.

A copy of the latest VIS for Multiple Vaccines is attached.

Administration

0.5 mL dose for intramuscular injection.

Storage and Handling

Vaxelis™ should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze.

Administration with Other Vaccines

Vaxelis™ can be administered at the same visit as other indicated vaccines.

POTENTIAL VACCINE ADVERSE EVENTS

The most commonly solicited adverse reactions following any dose were irritability, crying, injection site pain, somnolence, injection site erythema, decreased appetite, fever, injection site swelling, and vomiting.

REPORTING OF SUSPECTED VACCINE ADVERSE EVENTS OR ERRORS

Providers should report suspected adverse events to Vaxelis™ or any other vaccine to the Vaccine Adverse Events Reporting System (VAERS) at 800-822-7967 (toll-free) or <http://vaers.hhs.gov>.

Providers should report any vaccine administration error and associated contributing factors to the National Vaccine Errors Reporting Program (VERP) at <http://verp.ismp.org/>. As a part of the report, providers can make recommendations for error prevention. This surveillance program aims to prevent future errors by identifying trends, creating targeted education efforts, and making changes to product labeling and design.

HOW SUPPLIED

Vaxelis™ is supplied in a single-dose vial of 0.5 mL in packages of 10 vials (NDC 63361-0243-10) and as a single-dose, prefilled syringe of 0.5 mL with Luer lock connection and a tip cap, without needle, in packages of 10 (NDC 63361-0243-15). The vial stopper, syringe plunger stopper, and syringe tip cap are not made with natural rubber latex.

ORDERING AND BILLING

VFC Ordering

VFC Providers may now order Vaxelis™ through their [MyVFCvaccines](#) account. The other combination DTaP, IPV, Hib, HepB products listed in the table below are currently available for ordering through the California VFC Program.

Vaccine	Trade Name	Manufacturer	Primary Series	Booster
DTaP, IPV, Hib, HepB	Vaxelis™	Merck/Sanofi	2, 4, 6 months	
DTaP, IPV, Hib	Pentacel®	Sanofi	2, 4, 6 months	15 months
DTaP, IPV, HepB	Pediarix®	GlaxoSmithKline	2, 4, 6 months	

If your practice plans on switching to Vaxelis™ from another vaccine product, submit a [“Provider Request Form to Update Vaccine Brand Products Administered”](#) to the VFC Program and keep the following information in mind:

- Careful consideration should be given when selecting alternative brands or products in order to minimize the impact on provider practices.
- Implementation of a different vaccine brand or product should be approved by your practice’s medical director or Provider of Record.
- Staff should be thoroughly informed and educated on changes to vaccines and its impact on vaccine ordering, storage, administration, and documentation.
- As your practice transitions to a new product, managing on-hand inventory appropriately is a key factor in preventing unnecessary vaccine wastage. Your initial request for a new vaccine product may be reduced to help minimize vaccine waste as you transition from the product currently being used by your practice.
- A plan to deplete excess inventory must be in place prior to transitioning to a new product. It is the provider’s responsibility to ensure all VFC-supplied vaccines are used prior to its expiration date or transferred to another VFC Provider who can use them. Viable unused doses of these individual vaccines cannot be returned to the VFC Program.

Billing Information for VFC Vaccine

CHDP Claims may be submitted for VFC-supplied doses of Vaxelis™ administered to CHDP-eligible patients through age 18 years. Please refer to the CHDP Provider manual and relevant [CHDP Provider Information Notice](#).

CHDP providers with additional questions are advised to contact their [County CHDP Program](#) (<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 Vaxelis™, use the appropriate CPT-4 code 90697 (diphtheria, tetanus

toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenzae type b PRP-OMP conjugate vaccine, and hepatitis B vaccine [DTaP-IPV-Hib-HepB], for intramuscular use), followed by the “-SL” modifier. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS eligible patients. The CPT code for administration of Vaxelis™ by VFC providers for Medi-Cal is **90697-SL**.

For specific information and details on Medi-Cal billing, please refer to the [Medi-Cal provider manual on VFC](#). 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 Vaxelis™ that is not supplied by VFC

- The CPT-4 code for Vaxelis™ is **90697** (diphtheria, tetanus toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenzae type b PRP-OMP conjugate vaccine, and hepatitis B vaccine [DTaP-IPV-Hib-HepB], for intramuscular use)
- The ICD-10-CM code for an encounter for immunization is **Z23**.

DOCUMENTATION

[Vaccine Information Statement \(VIS\)](#): The latest VIS for Multiple Vaccines can be found at <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/multi.pdf>.

[EZIZ Vaccine Fact Sheet](#): One-page, quick-reference fact sheet that provides information about schedules, minimum intervals, age ranges, administration routes, billing codes, storage, and more: <https://eziz.org/resources/vaccinefactsheets/>

[FDA Product Insert](#): Refer to the product package insert for Vaxelis™ for additional vaccine information: <https://www.fda.gov/vaccines-blood-biologics/vaxelis>

[VFC Resolution No. 10/19-1 \(Vaccines to Prevent Diphtheria, Tetanus and Pertussis\)](#): The VFC resolutions for Vaxelis™-containing vaccines may be found at <https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>.

[ACIP DTaP-IPV-Hib-HepB vaccine recommendations](#): ACIP recommendations for DTaP-IPV-Hib-HepB vaccine use are posted at <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/dtap-ipv-hib-hepb.html>.

[AAP vaccine recommendations](#) and other information about DTaP-IPV-Hib-HepB vaccines are available to AAP members at <http://www.cispimmunize.org/>.

[General Recommendations on Immunization](https://www.cdc.gov/vaccines/hcp/acip-recs/index.html) (includes minimum ages and intervals) may be found at <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

[Vaccine Injury Compensation Program \(VICP\)](http://www.hrsa.gov/vaccinecompensation/): Vaxelis™ is covered by the federal VICP. Information on the federal VICP and DTaP-IPV-Hib-HepB vaccines may be found at <http://www.hrsa.gov/vaccinecompensation/>.

Additional information on vaccines and vaccine preventable diseases can be found at <http://www.cdc.gov/vaccines/>.