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

KAREN L. SMITH, MD, MPH
Director and State Health Officer

EDMUND G. BROWN JR.
Governor

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TO: California Vaccines for Children (VFC) Program Providers

FROM: Sarah Royce, M.D., M.P.H, Chief
Immunization Branch

SUBJECT: HIBERIX™ (HAEMOPHILUS INFLUENZAE TYPE B (HIB) CONJUGATE VACCINE) AVAILABLE FOR BOTH PRIMARY SERIES AND BOOSTER DOSE

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

SUMMARY

On January 14, 2016, the United States Food and Drug Administration (FDA) expanded the licensure of Hiberix™ (GlaxoSmithKline Biologicals [GSK]). It is now licensed for the primary Hib vaccination series at 2, 4, and 6 months of age, in addition to the previous indication for the booster dose. Hiberix™ is a *Haemophilus influenzae* type b conjugate (tetanus toxoid conjugate) vaccine indicated for active immunization for the prevention of invasive disease caused by *Haemophilus influenzae* type b for children 6 weeks through 4 years of age.

The Advisory Committee on Immunization Practices (ACIP) recommends Hib vaccination for children with the primary series at ages 2 months, 4 months, and 6 months with a booster recommended at 12 through 15 months.

Hiberix™ (Hib conjugate [PRP-T]) may now be used as an option for both the primary Hib vaccine series and booster dose in the California VFC Program. This document summarizes information about the use of Hiberix™ in the VFC program and summarizes Hib immunization recommendations.

BACKGROUND AND COMPOSITION

Hiberix™ is a *Haemophilus influenzae* type b (Hib) conjugate vaccine composed of *H. influenzae* type b capsular polysaccharide (polyribosyl-ribitol-phosphate) conjugated to inactivated tetanus toxoid (PRP-T). Hiberix™ is supplied as a lyophilized powder for reconstitution with sterile 0.9% saline solution which is supplied in a vial. Hiberix™ does not contain thimerosal or latex (in the vial stopper).

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of Hiberix™

VFC supplies of Hiberix™ may be given to any VFC-eligible child ages 6 weeks through 4 years for the primary series and booster dose. VFC supplies of Hiberix™ may also be given to VFC-eligible children and adolescents though age 18 years with high-risk conditions, per the VFC resolution and ACIP recommendations.

Licensed Dosing Schedule

Hiberix™ is licensed to be given as both the Hib primary immunization series (at 2, 4, and 6 months) and the booster dose (at 15 through 18 months) for children 6 weeks through 4 years. The ACIP recommends the Hib booster dose at ages 12 through 15 months. The final dose of Hiberix™ may be administered as early as age 12 months if the minimum interval of 8 weeks has been met since the last dose of Hib vaccine. Please see the ACIP recommendations and VFC resolution for further information on Hib vaccine administration, including immunization schedules for late doses and immunization of high-risk persons.

Current ACIP Recommendations

Hib vaccine is recommended for the following groups:

- Infants should receive their primary Hib series at ages 2, 4, and 6 months with a Hib booster dose at 12 through 15 months of age.
- Persons with high-risk conditions, including those undergoing chemotherapy or radiation treatment or who have anatomic or functional asplenia (including sickle cell disease), HIV infection, immunoglobulin deficiency, or early component complement deficiency should also be vaccinated. See ACIP recommendations for further details.

Minimum Ages and Intervals

- Minimum age: 6 weeks
- Minimum intervals for primary series (up to 12 months): 4 weeks
- Minimum age for booster: 12 months
- Minimum interval between last dose of the primary series and the booster dose: 8 weeks

Contraindications

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of Hib-containing vaccine, any ingredient of Hiberix™ vaccine, or tetanus toxoid-containing vaccine
- Infants younger than 6 weeks of age

Precautions

- Moderate to severe acute illness

For additional information, see the FDA product information:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm179527.htm

Hib or Multiple Vaccine(s) Information Statement (VIS)

The most current version of the *Haemolphilus influenza* Type b (Hib) Vaccine or Multiple Vaccines Vaccine Information Statement must be provided to a parent or guardian before the child receives each dose of Hib vaccine. Each time a VIS is provided the following information must be included in each patient's permanent medical record:

(1) Edition date of the current Vaccine Information Statement that was provided.
(2) Date that the VIS was provided.

A copy of the latest Hib VIS is attached.

Administration

Hiberix™ should be reconstituted only with the accompanying 0.9% saline diluent (see product information for details or manufacturer's website for more information [http://www.hiberix.com/packaging-dosage-administration.html]). **Do not** use any other sterile liquid or other sterile saline diluent (e.g., 0.4% saline diluent [vial] used for ActHIB®) to reconstitute the lyophilized Hiberix™ vaccine. If another diluent is used, the dose should not be counted as valid. Reconstituted vaccine should be administered **intramuscularly**.

Storage and Handling

It is extremely important to carefully store the diluent and lyophilized powder with VERY clear labeling so that the Hiberix™ vial containing the 0.9% saline diluent is used to reconstitute the lyophilized Hiberix™ (vial).

Vaccine should be stored between 2 and 8 ºC (36 and 46 ºF). Store diluent refrigerated at 2 to 8 ºC (36 to 46 ºF) or at a controlled room temperature below 25 ºC (below 77 ºF). Do not freeze diluent.

Administration with Other Vaccines

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

POTENTIAL VACCINE ADVERSE EVENTS

The most commonly reported adverse events were injection site pain, irritability, and drowsiness; rates were similar for Hiberix™, ActHIB®, and Pentacel®.

REPORTING OF SUSPECTED VACCINE ADVERSE EVENTS OR ERRORS

Providers should report suspected adverse events to Hiberix™ 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

Hiberix™ is provided in a ten dose package containing ten vials of lyophilized vaccine and ten 0.85 mL vials of saline (0.9%) diluent.

ORDERING AND BILLING

VFC Ordering

Hiberix™ is now available for VFC Providers to order through their MyVFCvaccines account. The four Hib-containing vaccine products listed in the table below are currently available for ordering through the California VFC Program. Please note that the primary series consists of two doses of PedvaxHIB® as compared to three doses for ActHIB®, Hiberix™, or Pentacel®.

Vaccine	Trade Name	Manufacturer	Primary Series	Booster
Hib	Hiberix™	GSK	2, 4, and 6 months	12-15 months
Hib	PedvaxHIB®+	Merck	2 and 4 months	12-15 months
Hib	ActHIB®	Sanofi	2, 4, and 6 months	12-15 months
DTaP-IPV/Hib	Pentacel®	Sanofi	2, 4, and 6 months	12-15 months

+Can be used for all children, but should especially be targeted for use in American Indian/Alaska Native (AI/AN) children living in AI/AN communities.

Offices must choose only one non-combination Hib vaccine formulation for use (ActHIB®, PedvaxHIB®, or Hiberix™) to avoid confusion. ActHIB® and Hiberix™ are both lyophilized Hib vaccines; however, their diluents are NOT interchangeable. Vaccine requests for more than one of the available Hib products will not be processed.

Billing Information for VFC Vaccine

CHDP
Claims may be submitted for VFC-supplied doses of Hiberix™ 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 *Haemophilus influenza* type b vaccine from the CHPD 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 Hiberix™, use the appropriate CPT-4 code, 90648, 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 Hiberix™ by VFC providers for Medi-Cal is **90648-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 Hiberix™ that is not supplied by VFC

- The CPT-4 code for Hiberix™ is **90648 (***Haemophilus influenzae* type b [Hib]-tetanus toxoid conjugate).
- The ICD-10-CM code for an encounter for immunization is **Z23**.

DOCUMENTATION

Vaccine Information Statement (VIS) and fact sheet: The latest Hib and Multiple Vaccines VIS sheet can be found at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html. Additional information on vaccines and vaccine preventable diseases can be found at: http://www.cdc.gov/vaccines/.

FDA Product Insert: Refer to the product package insert for Hiberix™ for additional vaccine information. This may be found at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm179527.htm.

VFC Resolution No. 2/13-2 (Vaccines to Prevent *Haemophilus influenzae type b*):
The VFC resolutions for Hib-containing vaccines may be found at:
https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html

ACIP Hib vaccine recommendations: ACIP recommendations for Hib vaccine use are posted at: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html.

AAP vaccine recommendations and other information about Hib vaccines are available to AAP members at: http://www.cispimmunize.org/.

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

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