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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: Bexsero® (MenB-4C) and Trumenba® (MenB-FHbp) Meningococcal Serogroup B (MenB) Vaccines Are Now Available from VFC

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SUMMARY

This letter summarizes information about the use of two meningococcal B (MenB) vaccines based on the VFC resolution for MenB vaccines and Advisory Committee for Immunization Practices (ACIP) recommendations for MenB vaccines for persons at increased risk of meningococcal serogroup B disease. Final ACIP recommendations for MenB vaccines for use in persons without high-risk conditions are pending final publication in the Morbidity & Mortality Weekly Report (MMWR). The California VFC Program will provide updates if needed after final publication.

On October 29, 2014, the United States Food and Drug Administration (FDA) licensed Trumenba® (MenB-FHbp [Pfizer, Inc.]) as a three-dose meningococcal serogroup B (MenB) vaccine series. On January 23, 2015, the FDA licensed Bexsero® (MenB-4C [Novartis Vaccines and Diagnostics/GlaxoSmithKline]) as a two-dose MenB vaccine series. Both MenB vaccines were licensed based on an accelerated approval process. Both vaccines are indicated for use in persons 10 through 25 years of age and are indicated for the protection against invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B. The ACIP voted to recommend either Bexsero® and Trumenba® for groups of persons, 10 years or older, at increased risk for serogroup B meningococcal disease at the February 2015 ACIP meeting. At the June 2015 ACIP meeting, ACIP voted that all persons without high-risk conditions ages 16

through 23 years may also be vaccinated with MenB vaccines. The two vaccines are now available from VFC for persons 10 through 18 years at increased risk for meningococcal serogroup B disease and for persons 16 through 18 years without high risk conditions.

BACKGROUND AND COMPOSITION

Neisseria meningitidis (meningococcus) is a gram-negative diplococcus that causes severe invasive infections such as sepsis and meningitis. Meningococci are classified by serogroups based on the polysaccharide capsule. There are several currently licensed meningococcal conjugate vaccines. FDA-licensed quadrivalent meningococcal conjugate vaccines (e.g., Menveo[®] and Menactra[®]) protect against serogroups A, C, Y, and W-135. FDA-licensed MenHibrix[®] (HibMenCY) is a conjugate vaccine that protects against serogroups C and Y (as well as *Haemophilus influenzae* type b). These licensed meningococcal conjugate vaccines do not protect against serogroup B.

Protection against invasive meningococcal disease is conferred mainly by complement-mediated antibody-dependent killing of *N. meningitidis*. The ability of MenB vaccines to use complement-mediated antibody-dependent killing following vaccination is dependent on both the antigenic similarity of the bacterial and vaccine surface proteins as well as the amount of vaccine surface proteins expressed on the surface of the invading meningococci. Both vaccines were approved based on demonstration of immune response, as measured by serum bactericidal activity against three (Bexsero[®]) or four (Trumenba[®]) strains representative of prevalent strains in the United States.

Since there are two choices for MenB vaccines, the CDPH Immunization Branch encourages each provider to review information on both vaccines and to choose one vaccine for use in your practice. It is important to educate all staff regarding the storage, preparation, administration, dose schedule, and recordkeeping for any new vaccine used in your practice.

MenB-4C Vaccine

MenB-4C consists of three recombinant proteins (Neisserial adhesin A [NadA], factor H binding protein [FHbp], Neisserial Heparin Binding Antigen [NHBA]), and outer membrane vesicles (OMVs) containing outer membrane protein PorA serosubtype P1.4. These proteins are found on the surface of meningococci and contribute to the ability of the bacterium to cause disease. The antigens are adsorbed onto aluminum hydroxide. Each dose contains less than 0.01 micrograms kanamycin.

MenB-FHbp Vaccine

MenB-FHbp consists of two recombinant lipidated recombinant FHbp antigens, one from each FHbp subfamily (A and B). FHbp is one of many proteins found on the surface of meningococci and contributes to the ability of the bacterium to avoid host defenses. The proteins are produced in *E. coli* and then purified. The vaccine also contains aluminum phosphate.

RECOMMENDATIONS FOR USE OF BEXSERO[®] AND TRUMENBA[®] IN THE VFC PROGRAM

Eligible Persons for Receipt of VFC Supplies

VFC-eligible children aged 10 through 18 years at increased risk for meningococcal disease attributable to serogroup B¹, including:

¹ Microbiologists routinely exposed to isolates of *Neisseria meningitidis* are also at increased risk of meningococcal serogroup B disease but are not in the VFC-eligible age group.

- Persons who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D, or who are taking eculizumab [Soliris[®]])
- Persons with anatomic or functional asplenia, including sickle cell disease
- Children identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B.

VFC-eligible children aged 16 through 18 years without high-risk conditions may also be vaccinated.

Meningococcal Serogroup B Vaccine Recommendations

Persons aged 10 and older at increased risk for meningococcal disease attributable to serogroup B (for risk groups, see preceding VFC recommendations).

Persons aged 16 through 23 years without high-risk conditions may also be vaccinated with a serogroup B meningococcal (MenB) vaccine series to provide short-term protection against most strains of MenB disease.² The preferred age for MenB vaccination is age 16 through 18 years of age.² The same product should be used for all doses in a series.

Final ACIP recommendations will be published in the MMWR. Providers should review all details in the final ACIP meningococcal serogroup B recommendations once published.

Administration of Bexsero[®]

Bexsero[®] (MenB-4C) should be administered as a two-dose series (0.5 mL each) at least one month apart. The series should be completed with the same brand of MenB vaccine. Do not use Trumenba to complete the series.

Shake the syringe immediately before use to form a homogeneous suspension. Do not use the vaccine if it cannot be re-suspended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulate matter or discoloration is found.

Administer 0.5 mL as an intramuscular injection into the deltoid muscle of the upper arm.

Administration of Trumenba[®]

Trumenba[®] (MenB-FHbp) should be administered as a three-dose series (0.5 mL each) according to a 0-, 2-, and 6-month schedule. The series should be completed with the same brand of MenB vaccine. Do not substitute Bexsero[®].

Shake the syringe vigorously to ensure that a homogenous white suspension of Trumenba[®] is obtained. Do not use the vaccine if it cannot re-suspended. Inspect visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulate matter or discoloration is found.

Administer a 0.5 mL dose as an intramuscular injection into the deltoid muscle of the upper arm.

²This ACIP recommendation is pending publication in the MMWR. Recommendations are not considered official CDC recommendations until published in the MMWR.

General Guidance

Based on available data and expert opinion, MenB4C and MenB-FHbp may be administered concomitantly with other vaccines indicated for this age, but at a different anatomic site, if feasible.

Providers should report any vaccine administration error and associated contributing factors to the National Vaccine Errors Reporting Program (VERP) at <http://verp.ismp.org/>. Examples of potential errors include HPV2 (licensed only for females) administered to a male or DTaP administered to a teenager. 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 MEN B VACCINES ARE SUPPLIED FOR CALIFORNIA VFC PROGRAM PROVIDERS

MenB-4C (Bexsero®)

Bexsero® is supplied as a 0.5 mL suspension in a glass pre-filled syringe. One carton contains 10 syringes. The tip caps of the pre-filled syringes contain natural rubber latex, the plungers are not made with latex.

MenB-4C Storage

- Please keep all vials stored in the original carton.
- Bexsero® should be refrigerated at 36°-46° F (2°-8°C).
- Do not freeze. Discard if frozen.
- Protect from light.
- Do not use after the expiration date.

MenB-FHbp (Trumenba®)

Trumenba® is supplied as a prefilled syringe with 10 doses per package. The tip cap and rubber plunger of the prefilled syringe are not made with natural rubber latex.

MenB-FHbp Storage

- After shipping, Trumenba® may arrive at temperatures between 36°-77° F (2°-25°C)
- Please keep all vials stored in the original carton
- Upon receipt, store refrigerated at 36°-46°F (2°-8°C).
- Store syringes horizontally (laying flat on the shelf) to minimize re-dispersion time.
- Do not freeze. Discard if frozen.

POTENTIAL VACCINE REACTIONS

The most common adverse reactions after administration of MenB-4C were pain at the injection site, myalgia, erythema, fatigue, headache, induration, nausea, and arthralgia. The most common adverse reactions reported after administration of MenB-FHbp were pain at the injection site, fatigue, headache, myalgia, and chills. For additional information, please see FDA product labels and the hyperlinks below. Additional safety data on the two vaccines will continue to be collected and monitored.

Syncope can occur after vaccination, most commonly among adolescents and young adults. To avoid serious injury related to a syncopal episode, vaccine providers should consider observing

patients for 15 minutes after they are vaccinated. To decrease the risk of injury from syncope, providers should consider having their patients seated during both vaccination and the observation period.

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

CONTRAINDICATIONS

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to any component of the vaccine.

PRECAUTIONS

- MenB vaccines can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever).
- Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.

ORDERING AND BILLING

How to Order

Both meningococcal serogroup B vaccines are now available for ordering at MYVFCVaccines. Vaccines are displayed in the “Special Order Vaccines” Section of VFC’s order form.

In order to avoid confusion between both brands of MenB vaccines (given the different dose schedules), providers must choose to use only one brand. Orders for both available products will not be processed.

Ordering Considerations

Prior to ordering a new vaccine, please educate your entire staff administering and managing vaccines, as it will affect vaccine ordering, storage, administration, and documentation.

Providers are responsible for using all doses of VFC vaccines ordered. With a newly introduced vaccine, it is a good idea to start with a conservative estimate of doses needed. Start with the number of VFC-eligible patients aged 16 through 18 years in your practice and the frequency of their visits. If your practice has high risk patients between 10 and 16 years of age, you may also want to use these numbers to determine your initial order. Keep in mind that the number of doses you will be placing will be to meet the needs for patients to be immunized during your ordering period.

Billing Information for VFC Meningococcal Serogroup B Vaccines

Please see the Medi-Cal Provider Bulletin – General Medicine – July 2015 – Bulletin 493 for information about billing for MenB vaccines for VFC-eligible patients at increased risk of meningococcal serogroup B disease. Providers must use modifiers SK and SL with the respective CPT codes when billing for VFC claims for high-risk VFC recipients.

- The CPT code for MenB-4C (Bexsero[®]) is 90620.
- The CPT code for MenB-FHbp (Trumenba[®]) is 90621.

Additional information about billing for MenB vaccines for VFC eligible patients 16 through 18 years of age not at high risk will be forthcoming from the Department of Health Care Services.

- Medi-Cal Provider Bulletins http://files.medi-cal.ca.gov/pubsdoco/Bulletins_menu.asp.
- Medi-Cal Provider Manual http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/vaccine_m00o03o04o11.doc.

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. For questions on Medi-Cal Managed Care, please contact the specific Medi-Cal Managed Care Health Plan for specifics on billing and reimbursement.

Information for billing the Child Health and Disability Prevention (CHDP) program for MenB vaccines will be forthcoming from Department of Health Care Services.

- CHDP Provider Information Notices
<http://www.dhcs.ca.gov/services/chdp/Pages/CHDPPLPIN.aspx>.

CHDP providers with additional questions are advised to contact their County CHDP Program at <http://www.dhcs.ca.gov/services/chdp/Pages/CountyOffices.aspx>.

Other codes for the use of Bexsero[®] or Trumenba[®] that is not supplied by VFC:

- The CPT code for Bexsero[®] is **90620**.
- The CPT code for Trumenba[®] is **90621**.
- The ICD-9-CM code for the need for prophylactic vaccination against a specified bacterial disease is **V03.89**.

DOCUMENTATION - HYPERLINKS

1) ACIP recommendations:

- Recommendations for permissive use of MenB vaccines will be posted at: <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html>.
- [Use of Serogroup B Meningococcal \(MenB\) Vaccines in Persons Aged ≥10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2015](#)

2) FDA Product Inserts:

- [Bexsero[®]](#)
- [Trumenba[®]](#)

3) [Vaccine Information Statement \(VIS\)](#) for MenB vaccines.

4) [VFC resolution No. 06/15-1 on meningococcal vaccines](#)

5) [Medi-Cal Provider Bulletin - General Medicine - Jan 2015 - Bulletin 487](#)

6) AAP recommendations (members-only): <http://www.cispimmunize.org/>

7) Vaccine Injury Compensation Program (VICP): Meningococcal vaccines are covered by the [federal VICP](#).